Validation of the OHIP-EDENT Instrument using the Factor Analysis Technique

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DEDICATION

To those who inspired and supported me along this journey.

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LIST OF ABBREVIATIONS

- QoL: Quality of Life
- HRQoL: Health Related Quality of Life
- OHRQoL: Oral Health Related Quality of Life
- WHO: World Health Organization
- ICIDH: International Classification of Impairment, Disability, and Handicap
- PROs: Patient Reported Outcomes
- PROMs: Patient Reported Outcomes Measures
- dPROMs: Dental Patient Reported Outcomes Measures
- OHIP: Oral Health Impact Profile
- OHIP-EDENT: Oral Health Impact Profile for Edentulous Patients
- GOHAI: General Oral Health Assessment Index
- OIDP: Oral Impacts on Daily Assessment
- SIDD: Social Impact of Dental Disease
- DIP: Dental Impact Profile
- SOHSI: Subjective Oral Health Status Indicators
- OQoLQ: Orthognathic Quality of Life Questionnaire
- OHQoL-UK: UK Oral Health Related Quality of Life Measure
- RCT: Randomized Controlled Trial
- CDs: Complete Dentures
- IODs: Implant Overdentures
- EFA: Exploratory Factor Analysis
- CFA: Confirmatory Factor Analysis
- PCA: Principal Component Analysis
- KMO: Kaiser Meyer Olkein
- PAF: Principal Axis Factoring
- MINRES: Minimum Residuals
- ML: Maximum Likelihood
- ULS: Unweighted Least Squares
- RMSEA: Root Mean Square Error of Approximation
- TLI: Tucker Lewis Index
- CFI: Comparative Fit Index
- GFI: Goodness of Fit Index

- NFI: Normed Fit Index
- SRMR: Standardized Root Mean Square Residual

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ABSTRACT

Background

Oral Health Related Quality of Life (OHRQoL) plays a fundamental role in the overall well-being of an individual. The OHIP-EDENT questionnaire proposed by Allen and Locker evaluates OHRQoL in edentulous populations The original instrument comprises of 20 items across 7 domains which assess the functional, psychological, and social implications of being edentulous. While several authors have argued that the OHIP-EDENT scores accurately capture the latent construct of OHRQoL, conflicting findings in multiple studies challenge this idea. This results from the emergence of alternative-factor solutions with fewer domains documented in scientific literature, diverging from the originally postulated 7-factor solution of the OHIP-EDENT.

Objective

To estimate the extent to which the OHIP-EDENT accurately reflects OHRQoL using baseline data from two studies and evaluating the optimal factor structure which could potentially improve OHIP-EDENT's validity.

Methodology

The study draws on baseline data from participants in a US quasi-experimental study (N=165) and a Canadian randomized clinical trial (N=255), the Kaiser Meyer Olkin and Bartlett tests assessed sampling adequacy. The Exploratory Factor Analysis (EFA) on data from the US population identified the latent constructs of the OHIP-EDENT. After identifying the 3-factor structure from the EFA, a Confirmatory Factor Analysis (CFA) of the Canadian cohort data validated this hypothesized model. Factor analysis was performed on two separate datasets to ensure stability and generalizability of the 3-factor model. Subsequently, an additional step was carried out to evaluate the cross-cultural applicability of the OHIP-EDENT instrument. A 4-factor model (based on published literature) was tested on data of the Canadian population using CFA, and the 3-and 4-factor CFA models were compared.

Results

The EFA on the US population revealed a three-factor configuration of the OHIP-EDENT (Cronbach’s alpha = 0.946). This hypothetical three-factor model was applied to the Canadian cohort and the CFA results revealed excellent fit (RMSEA=0.043; CFI=0.995). The four-factor

solution from the Brazilian population also showed excellent results when tested in the Canadian cohort (RMSEA=0.037; CFI= 0.996).

Conclusion

The postulated 3-factor model identified constructs "Functional and Psychological Well-Being," "Social Impact," and "Physical Discomfort", while the 4-factor model included an additional construct, "Masticatory-related complaints", offering a more comprehensive framework to investigate the dimensions of OHRQoL in edentulous individuals.

RÉSUMÉ

Contexte

La qualité de vie liée à la santé bucco-dentaire (QVLS) joue un rôle fondamental dans le bien-être général d'un individu. Le questionnaire OHIP-EDENT proposé par Allen et Locker évalue la QVLS dans les populations édentées. L'instrument original comprend 20 questions réparties sur 7 domaines qui évaluent les implications fonctionnelles, psychologiques et sociales de l'édentation. Bien que plusieurs auteurs aient soutenu que les scores de l'OHIP-EDENT capturent avec précision le concept latent de la QVLS, les résultats contradictoires de plusieurs études remettent en cause cette idée. Cela s'explique par l'émergence de solutions à facteurs alternatifs avec moins de domaines documentés dans la littérature scientifique, divergeant de la solution à 7 facteurs de l'OHIP-EDENT postulée à l'origine.

Objectif

Estimer dans quelle mesure l'OHIP-EDENT reflète fidèlement l'OHRQoL en utilisant les données de base de deux études et en évaluant la structure factorielle optimale qui pourrait potentiellement améliorer la validité de l'OHIP-EDENT.

Méthodologie

L'étude s'appuie sur les données de référence des participants à une étude quasi-expérimentale américaine (N=165) et à un essai clinique randomisé canadien (N=255). Les tests de Kaiser Meyer Olkin et Bartlett ont permis d'évaluer l'adéquation de l'échantillonnage. L'analyse factorielle exploratoire (AFE) sur les données de la population américaine a permis d'identifier les concepts latents de l'ÉDENT-OHIP. Après avoir identifié la structure à trois facteurs à partir de l'EFA, une analyse factorielle confirmatoire (AFC) des données de la cohorte canadienne a validé ce modèle hypothétique. L'analyse factorielle a été réalisée sur deux ensembles de données distincts afin de garantir la stabilité et la généralisation du modèle à trois facteurs. Par la suite, une étape supplémentaire a été réalisée pour évaluer l'applicabilité interculturelle de l'instrument OHIP-EDENT. Un modèle à 4 facteurs (basé sur la littérature publiée) a été testé sur des données de la population canadienne à l'aide de l'AFC, et les modèles à 3 et 4 facteurs de l'AFC ont été comparés.

Résultats

L'AFE sur la population américaine a révélé une configuration à trois facteurs de l'instrument OHIP-EDENT (alpha de Cronbach = 0,946). Ce modèle hypothétique à trois facteurs a été appliqué à la cohorte canadienne et les résultats de l'AFC ont révélé une excellente adéquation (RMSEA = 0,043 ; CFI = 0,995). La solution à quatre facteurs de la population brésilienne a également donné d'excellents résultats lorsqu'elle a été testée dans la cohorte canadienne (RMSEA=0,037 ; CFI= 0,996).

Conclusion

Le modèle à trois facteurs postulés a identifié les construits « bien-être fonctionnel et psychologique », « impact social » et « inconfort physique », tandis que le modèle à quatre facteurs comprenait un construit supplémentaire, « plaintes liées à la mastication », offrant un cadre plus complet pour étudier les dimensions de l'OHRQoL chez les personnes édentées.

CONTRIBUTION OF AUTHORS

Amee Sanghavi, MSc. Candidate, Faculty of Dental Medicine and Oral Health Sciences, McGill University, Montreal, Quebec, Canada: Conceptualized study, carried out statistical analysis, interpretated findings and wrote manuscript.

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Thomas Nguyen, Assistant Professor, Faculty of Dental Medicine and Oral Health Sciences, McGill University, Montreal, Quebec, Canada: contributed to review and writing.

1. INTRODUCTION

Over the last few decades, the term “quality of life” and “health-related quality of life” have been used amongst the members of the scientific community in relation to the impact of disease and the effect of treatments provided for a particular health condition. [1] This concept emerged from the need to complement traditional clinical and laboratory measures with an individual’s assessment of intervention to identify important determinants of care-seeking behaviour and satisfaction with care. [2-3] This philosophy also applies to the field of dentistry and oral healthcare research. Oral Health-Related Quality of Life (OHRQoL) is essential for the overall well-being of an individual and is recognized by the World Health Organization (WHO) as a significant element of the Global Oral Health Program. [4] OHRQoL is a multidimensional construct with interactions between biological, social, psychological, and cultural factors. [5]

Numerous efforts have been made to develop instruments that measure OHRQoL since 1976 when Cohen and Jago formulated the first sociodental indicators. [6] There are several instruments available that evaluate different dental and oral health symptoms. One such instrument that is used to assess OHRQoL is the Oral Health Impact Profile (OHIP) which was specifically designed to evaluate the social impact of oral disorders, thus guiding better research and clinical decision-making. [7] Since OHIP is a detailed tool that covers several conceptual domains affected by pathological processes, there is a possibility to modify the original 49-item OHIP to understand and meet the expectations of a specific population in terms of OHRQoL. An example of such an adapted version is the Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT) tool which is used to evaluate OHRQoL in edentulous subjects, proposed by Allen and Locker. [8] The OHIP-EDENT tool, which consists of 19 items with questions in seven subscales (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap) retains the most significant questions from each original subscale. This shortened version is used because the full OHIP questionnaire is considered too lengthy and time-consuming for epidemiological studies. [9, 10] Previous studies have speculated that the shortened version of OHIP-EDENT, which includes fewer dimensions in comparison to the traditional seven domain framework have shown to capture key aspects of OHRQoL effectively. However, the evidence supporting this claim remains limited and inconclusive. My project aims to address this gap in the literature by evaluating whether the OHIP-EDENT instrument with fewer

domains effectively measures OHRQoL in edentulous populations and determining if an alternative framework provides a more effective measurement of the OHRQoL construct.

2. LITERATURE REVIEW

2.1 Patient Reported Outcomes (PROs):

Patient reported outcomes or PROs are defined by The Food and Drug Administration (2006) as “any report coming from a patient regarding a health condition and its treatment”. [11] PROs serve as essential indicators of treatment effectiveness, furnishing critical empirical data. This empowers researchers, clinicians and patients to make judicious and well-informed decisions about a specific therapeutic modality. [12] The evaluation of PROs dates back to the mid-1970s when health researchers interested in measuring health outcomes of chronic diseases recognized that these outcomes should be enhanced to encompass a broader range of aspects, including health related quality of life (HRQoL), patient satisfaction with respect to treatment, and adherence to medical regime. Since then, PROs have been systematically employed in numerous countries for clinical and policy research. [13-15] An important aspect of PROs is collecting information on health-related behaviors, such as consumption of tobacco, alcohol and other harmful substances, participation in physical activity, adhering to a diet regime, etc. [14] With the increase in awareness about patient-centered and holistic care, PROs have become an important tool to assess patient feedback on healthcare outcomes, as well as individual behavior change. [16] The concept of PROs focuses on the possibility for patients to express their perspectives on the symptoms of disease, associated treatment, and their interactions with the healthcare system.[17] In doing so, they provide valuable insights into the condition, its impact, and how it affects their daily functioning. This enables the patients to have greater autonomy in their treatment should they desire to be an active participant in their care.

However, the patient's awareness of the disease experience is often molded by their personal standards, intrinsic values, and expectations. Lohr et al. (2008) emphasized the different questions that would arise with the use of PROs. Despite the intent of PROs to accurately represent a person’s perceptions, we must be aware of the various factors that can affect the response, whether they will respond and, if they do, the timing, manner, and extent of the information they are willing to share. It has also been reported that social and environmental factors play a critical role during the collection of PROs. For instance, the relationship between the researcher-clinician and the patient may significantly impact the latter’s responses due to the perceived “hierarchical or social status” differential and can result in a response bias, thereby minimizing the “true representativeness” of a patient’s experience. [18-20]

Despite the numerous challenges encountered during the utilization of PROs, there is an inherent ethical context that aligns with the principles of patient autonomy and clinician beneficence or non-maleficence; this cannot be overlooked. PROs create a possibility of achieving a "fulfilling life", uniquely defined by each patient through facilitating enhanced communication and shared decision making between the patient and the healthcare provider. As our understanding of patient perspectives deepens through the measurement of PROs, healthcare professionals have the opportunity to address various gaps and disparities in access to high quality healthcare, thereby improving their ability to address healthcare inequities. [14]

2.1.1 Types of PROs:

PROs are used to measure a wide range of health-related concepts. The five most common themes often explored with the help of PROs are: i. health-related quality of life, ii. functional status, iii. symptoms and symptom burden, iv. health behaviors, v. patient healthcare experience. [21]

i. Health Related Quality of Life (HRQoL):

By definition, the term Health-Related Quality of Life (HRQoL) falls under the umbrella term Quality of Life (QoL) which is defined as a multidimensional concept encompassing physical, psychological, social and emotional well-being in relation to disease and its associated treatment. [22] HRQoL measures also include individual perspectives, their ability to perform various roles, their social well-being, and their overall sense of wellness. These measurements may also extend to aspects like spirituality, sexual function, life satisfaction, and environmental factors. [23] HRQoL instruments are useful for measuring specific issues. For example, some HRQoL measures include questions on self-care. Answers to these questions may shed light on various aspects of an individual's well-being such as physical well-being (how the body functions), the impact of one's surroundings (such as having a home with accessible bathing and toileting facilities), and the ability to engage in social activities. [24]

ii. Functional Status:

In 1980, the WHO International Classification of Impairment, Disability, and Handicap (ICIDH), defined functional status assessment as the measure of the impact of disability. Functional status measurement is, therefore, crucial in the overall assessment of patient reported outcomes. In simple terms, functional status may be defined as the person's ability to carry out both basic and more advanced tasks on a day-to-day basis. An individual may be considered differently abled when essential activities are limited in nature, duration or quality of performance. [25] Prior to evaluating the functional status, clinicians and researchers should

determine whether symptoms of illness preceded a change in function and HRQoL [26] This assessment is necessary to establish causality between symptoms, function and HRQoL, which would help the clinician use the most appropriate tools and correctly interpret the PROs. A conceptual model proposed by Wilson and Cleary described the relationship between biologic and physiologic phenomena and how it can impact functioning domains such as physical, psychological and social functioning. [27-28] The combined impact of these effects leads to the development of an individual's perception of his/her HRQoL and well-being.

iii. Symptoms and Symptom burden:

The word, "symptom", has been defined in Webster's Third New International Dictionary as "the subjective evidence of disease or physical disturbance observed by a patient. A symptom is an observation of a patient's experience in relation to an illness or a physiological disturbance, that provides valuable insight to a clinician. [29] The concept of symptom burden arises due to the difficulty in determining the etiology of a particular symptom. It may arise due to the disease process itself or because of disease treatment and management. [30] Several tools are being developed to capture the essence of symptom burden, as well as to identify the symptoms that are most distressing for an individual's overall well-being. [31] Examples of symptom measurement scales include the Symptom Distress scale, the Memorial Symptom Assessment Scale, the Rotterdam Symptom Checklist, and the Edmonton Symptom Assessment System. [32-35] Each of these scales help to identify symptoms and symptom burden that would otherwise not be captured from a standard medical checkup. Thus, these self-reported measures can play a potential role in contributing to a person's overall well-being.

iv. Health behaviors:

Another construct often assessed through patient reported outcomes is health behaviors An individual's history of health behaviors over their lifetime plays a crucial role in determining their present, as well as future, HRQoL. Gochman (1982) defined health behaviors as "Personal attributes such as beliefs, expectations, motives, values, perceptions, and other cognitive elements; personality characteristics, including affective and emotional states and traits; and overt behavioral patterns, actions and habits that relate to health maintenance, to health restoration and to health improvement." [36] The most common cause of mortality across the globe are chronic diseases including cardiac disease, diabetes mellitus, hypertension, lung disease, and cancer. The onset of these chronic diseases is often associated with certain deleterious behavioral patterns or habits including tobacco and alcohol use, limited physical activity, diet comprising of highly processed food and engaging in inappropriate sexual

practices. [37-38] Information regarding health behaviors captured through PROs may help clinicians to identify both beneficial, as well as adverse, health related behaviors and plan individual care more efficiently.

v. Patient Experience of Care

With the continued expansion of the healthcare industry, the evaluation of healthcare organizations' performance and quality should be taken into consideration.[39] There is a growing recognition of the concept of "person-centeredness" and "patient-centered care" which has proven to be beneficial for two main reasons. Firstly, patients have autonomy and are fully engaged in their utilization of the healthcare services. Secondly, person-centered care is linked to enhanced healthcare utilization and improved health outcomes.[40]

The patient experience is a measure that reflects the quality of care provided and focuses on three main aspects: effective communication, respect and dignity, and emotional support. [41-42] Several factors, such as the characteristics of the healthcare facility (e.g., patient volume, healthcare provider to patient ratio, and available resources), patients personal attributes (e.g., medical history and previous experiences with healthcare), and the type of care received (whether its preventive, non-emergency or emergency care) can directly impact an individual's perception of quality of care. These factors can also indirectly shape a patient's experience by influencing their needs, expectations and values. [43]

2.1.2 Importance of PROs:

Collecting PROs is essential to provide a comprehensive understanding of the patient's experience. It fosters patient-centered care by offering direct insights into individuals' perceptions of their health and the impact of diseases or treatments on their daily lives. This information is crucial in tailoring patient-centered treatment planning, as well as providing interventions that align with an individual's needs and preferences. It also enhances a holistic approach to healthcare by incorporating the person's voice and experiences into scientific and clinical assessments.

i. Importance of PROs in Medicine:

Historically, PROs of HRQoL were primarily employed at the aggregate level, such as through observational studies and clinical trials. [44] However, there is a growing interest in utilizing these types of outcomes to provide for more patient-centered and holistic care. For example, several studies have reported a positive impact on cancer patients who routinely completed PROs and other QoL measures, along with open and effective communication with their

healthcare providers. [45-46] Additionally, the use of PROs in a clinical setting has been shown to be feasible and beneficial. Several studies have determined that the clinical integration of PROs not only enhances active participation amongst all involved parties, but also does not extend the duration of clinic visits, thereby improving provider and patient satisfaction rates. [47-48] It has been observed that some PRO instruments are intended for generic use, irrespective of the condition of the patient and, therefore, can also be completed by healthy individuals. These individuals may participate in a population or sample survey or as a part of a validation study to evaluate the tool or instrument being evaluated. [49] Some examples of a generic questionnaire that captures the health status of an individual include: the EuroQoL, the Medical Outcomes Study-36 Item Short Form, the Nottingham Health Profile and the Sickness Impact Profile. [50-53] There are several PRO instruments that are designed specifically to measure the impact of disease and study various symptoms throughout the course of the disease. Some examples include: the Functional Assessment of Cancer Therapy- General, the Pediatric Asthma Quality of Life Questionnaire, the Hospital Anxiety and Depression Scale, the McGill Pain Questionnaire, the Multidimensional Fatigue Inventory and the Barthel Index of Disability. [54-59]

ii. Importance of PROs in Dentistry:

Dental PROs are different than those observed in the field of medicine. Instruments that capture these are referred to as Dental Patient Reported Outcome Measures (dPROMS). [60] Patients generally express concerns that are related to specific aspects of their oral health, in particular: a. dental and orofacial pain, b. functional limitations with respect to jaw movement, c. concerns about compromised dental and orofacial esthetics, d. broader psychosocial concerns related to oral diseases. These 4 constructs can be collectively grouped under the concept of Oral Health Related Quality of Life (OHRQoL). [18] For individuals dealing with common oral health conditions, such as dental caries and periodontal disease, mortality outcomes hold little relevance. Instead, focus for dental patients shifts towards understanding the impact of oral diseases on their daily routine and how these affect their quality of life. This emphasis is particularly pronounced given the chronic nature of most dental conditions. [61]

2.2 Quality of Life (QoL):

The WHO describes the concept of QoL as a subjective assessment of an individual's perspective on life based on their inherent values and cultural beliefs. The Quality-of-Life

Research Unit at the University of Toronto defines QoL as "how much a person can enjoy the valued possibilities of their lives." QoL can be considered as an umbrella term which describes several aspects of an individual's well-being: personal health (physical, mental, and spiritual), relationships, education, professional environment, social status, wealth, a sense of security and safety, freedom, autonomy in decision-making, social-belonging and their physical surroundings. [62] QoL consists of 2 fundamental components: subjectivity and multidimensionality.

i. Subjectivity:

Subjectivity arises from the notion that the QoL is comprehensible solely through the lens of an individual's perspective. In oral healthcare, patients play a crucial role during the treatment planning stages, ensuring that their perspectives guide the selection of strategies which could potentially enhance their quality of life. [63] While measuring QoL, it is important to assess both the extent of dysfunction and satisfaction of a particular intervention or strategy within the realm of the patient's principles. A value-based rating is essential as it provides insights to care providers about a patient's subjective opinion on whether the dysfunction is acceptable and what strategies can be adopted to improve them.

ii. Multidimensionality:

QoL is a multidimensional construct which measures an individual's well-being across physical, psychological, emotional and spiritual aspects. There have been numerous attempts to adequately classify the various dimensions of QoL. However, the QoL model proposed by Schnipper and Levitt (1) encompassing physical/occupational function; (2) psychological state (3) sociability and (4) somatic comfort appears to encapsulate the concept comprehensively. [64-65]

iii. Importance of Quality-of-Life Measurement:

Clinicians and researchers are interested in evaluating quality of life in patients for three primary reasons: (a) to evaluate rehabilitation requirements; (b) to appraise treatment efficacy.

a. To evaluate rehabilitation requirements:

Patients often grapple with a myriad of physiological and psychological challenges that impact their overall well-being and quality of life. Inventories which help in identifying specific problems and categorize them into manageable groups can significantly aid clinicians, especially those with limited resources, in facilitating optimal treatment planning and patient management. [66] In regard to oral health conditions, edentulism has a significant impact on the overall quality of life of an individual. Edentulism can influence not only physical function,

but also psychological aspects related to self-image and expectations. In such cases, it is important to implement meticulous and validated instruments (eg. GOHAI and OHIP-EDENT) that are sensitive enough to detect problems across multiple domains. Upon identifying disruptions in the quality of life, targeted interventions can be implemented to enhance overall well-being. [67-68]

b. To appraise treatment efficacy:

The predominant reason for measuring quality of life in patients is to obtain a more holistic understanding of a particular health outcome. This provides us with an opportunity to analyze and compare QoL in patients across different treatment groups. Since edentulism is a chronic and a multifactorial condition, the existing therapeutic modalities tend to be more concerned with esthetics and functional efficiency as well as long-term stability of the prosthesis. [69]

2.2.1 Oral Health Related Quality of Life (OHRQoL):

Oral Health Related Quality of Life is a relatively newer concept which strives to offer comprehensive and patient-centered dental care while taking the patient's perspectives and lived experiences into consideration. OHRQoL has been defined as "a multidimensional construct that reflects (among other things) people's comfort when eating, sleeping, and engaging in social interaction; their self-esteem; and their satisfaction with respect to their oral health." [70] Traditionally, dentists have received training focused on diagnosing various oral diseases and conditions such as dental caries, periodontal disease, edentulism, head and neck tumors, etc. However, this conventional approach of training dental professionals does not encompass the broader perspective of assessing the impact of the disease itself on the overall well-being of an individual. [71] Incorporating the evaluation of OHRQoL into routine dental practice allows for transition from traditional treatment to a more inclusive approach centered on an individual's social and emotional well-being, to establish a suitable treatment plan that meets the patients' expectations. [72] Ever since, there has been a conflict in understanding how various health and oral health conditions could potentially impact the overall quality of life. For instance, Locker proposed that diseased state may not necessarily diminish the quality of life. This was further explained by how people suffering from chronic disorders may perceive their quality of life to be at par or even better than that of healthy individuals. [73] This phenomenon was further clarified by Allison et al. describing how "quality of life is a dynamic construct" and changes with time depending on an individual's attitudes, experiences and expectations.[74]

2.2.1.1 Models of Oral Health Related Quality of Life:

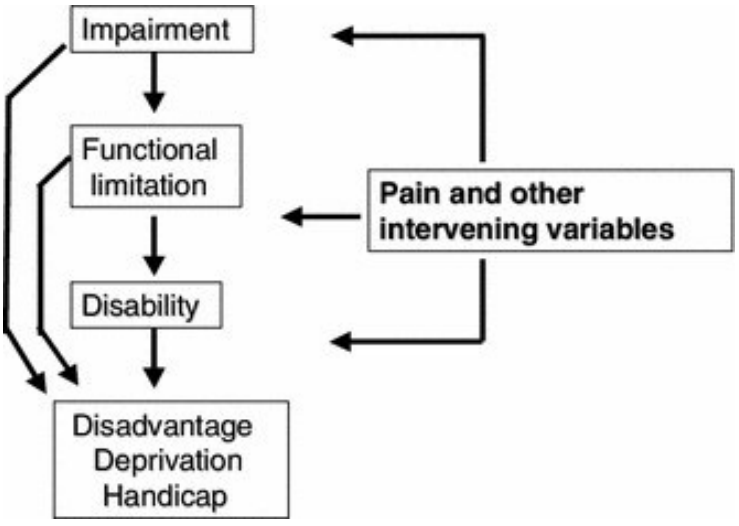
The existing oral health models have not addressed the overall spectrum of health outcomes associated with oral disabilities, and instead focus on the disease condition. The conceptual foundation in oral health research is centered around a biomedical approach, concerning diagnoses and pathologies. [75-76] Ever since, several models have been published in the literature to best encompass all the dimensions or concepts involved in defining Oral Health Related Quality of Life. A few examples of various models are as follows:

i. Model of Oral Health proposed by Locker in 1988:

The different indicators of OHRQoL are based on the theoretical framework proposed by the International Classification of Impairments, Disabilities and Handicaps (ICIDH) developed by WHO in 1980. [77]

This framework was later adapted by Locker in 1988, becoming the most implemented OHRQoL model in the field of dentistry. In this model, oral health concerns are depicted as linear and irreversible relationships between oral disease, disability and handicap, whereas pain and other variables serve as intervening factors (Fig 1). For example, people with tooth loss have restrictions due to limited function and may also experience speech and esthetic difficulties. While the model acknowledges that an impairment may not necessarily result in disability, it does not consider the possibility that the affected individuals can mitigate and even reverse the limitations through various coping strategies. [78]

Figure 1: Model of Oral Health proposed by Locker (1988)

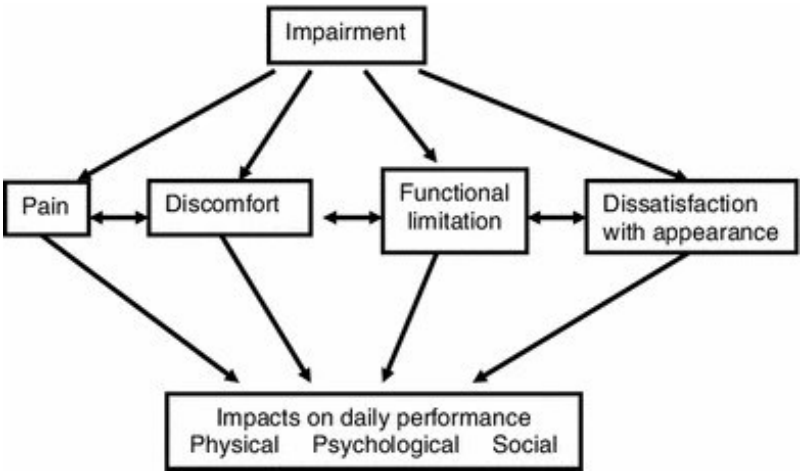


ii. Theoretical Framework of Oral Impact on Daily Performances proposed by Adulyanon and Sheiham in 1997:

The OHRQoL conceptual model proposed by Adulyanon and Sheiham (Fig 2) integrates elements from both the International Classification of Impairments, Disabilities and Handicaps

and the Locker model. Additionally, variables such as pain and dissatisfaction with appearance were included in the model to emphasize the role of the psychosocial impacts on daily functioning. The 3 psychosocial domains included in the model were termed as “Impacts on Daily Performances”, “Psychological” and “Social”. [79] This model offers an insight into assessing the repercussions of oral disorders and has served as a foundation for Cushing et al. to develop the Social Impacts of Dental Disease Questionnaire. [80]

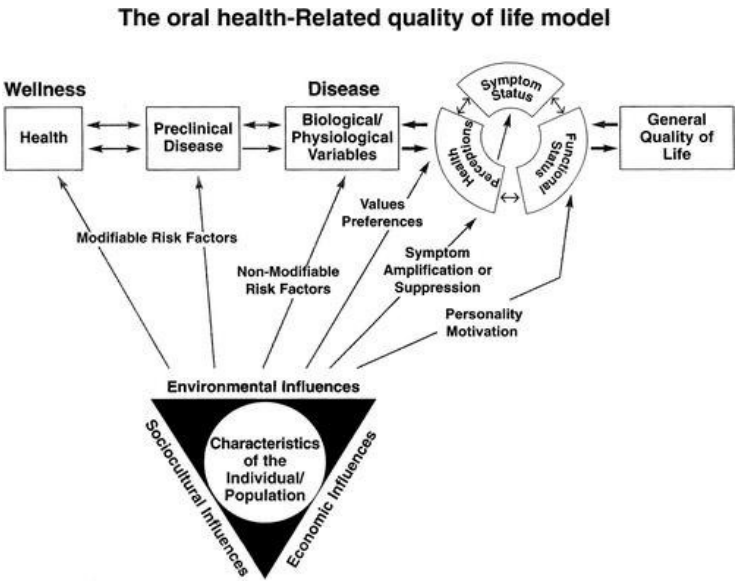
Figure 2: Theoretical Framework of Oral Impact on Daily Performances proposed by Adulyanon and Sheiham (1997)



iii. Model for Dental Hygiene proposed by William et al. in 1998:

The conceptual framework proposed by William et al. (Fig 3) is based on three existing health care models: the Wilson & Cleary HRQL model; the Natural History of Disease Model; and Neuman's Systems Model for Nursing. [81-83] The model was developed to aid dental hygienists in the accurate assessment and planning of dental hygiene care. The model portrays an association between six domains, each influencing one another. These include health/preclinical disease, biological/clinical disease, symptom status, functional status, health perception, and quality of life. Unlike previous OHRQoL models which exhibit a linear relationship between the variables, the current model highlights the evolving nature of oral health through bidirectional arrows, signifying continuous fluctuations. The model is grounded in prioritizing optimal oral health, comfort and function, as perceived by individuals and populations, recognizing these as a fundamental component of overall well-being. Furthermore, the model focuses on the significance of the oral cavity as a source of sensory input across all phases of life, and therefore its crucial role in social interaction and functioning. [84]

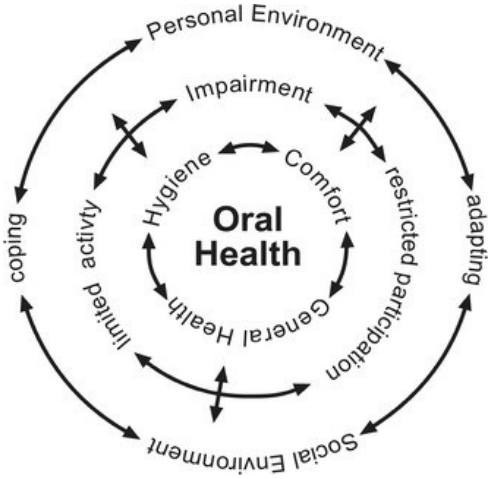
Figure 3: Model for Dental Hygiene proposed by William et al. (1998)



iv. Existential Model of Oral Health proposed by MacEntee in 2006:

The theoretical basis for MacEntee's model (Fig 4) was derived from individual qualitative interviews with the elderly population who acknowledged the pivotal role of oral health in personal and social well-being. [85] The model has integrated the diverse perspectives of all participants who were encouraged to express their thoughts on the importance of oral health through several open-ended questions. Through these qualitative interviews, MacEntee recognized that although the participants expressed the presence of oral disorders, they did not necessarily lead to dysfunction. The model aims to present a more positive outlook on how older individuals view oral health and illness as well as the importance of recognizing how various constituents of the model are equally important in defining the concept of OHRQoL. [86]

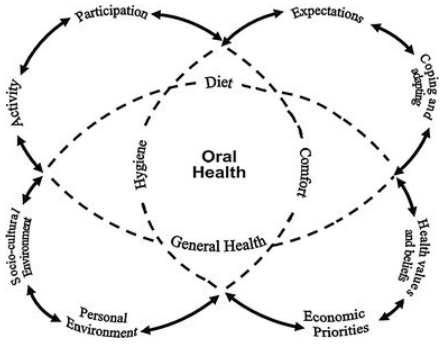
Figure 4: Existential Model of Oral Health proposed by MacEntee (2006)



v. Refined Model of the Key Components Relating to Oral Health proposed by Brondani et al. in 2007:

This model (Fig 5) is an adaptation of the Existential Model of Oral Health proposed by MacEntee. Brondani et al. suggested the implementation of focus groups that would facilitate discussions amongst the elderly individuals, resulting in a more comprehensive model that aligns with the participants oral health values and beliefs. [87] Therefore, the refined model elaborates on MacEntee's core elements of oral health, now illustrated by four orbiting ellipses that are non-hierarchical. These ellipses represent the impact of (1) personal and social environment, (2) activities and participation, (3) coping, adaptation, and expectations, and (4) economic priorities and health values and beliefs on oral health. Additionally, the participants suggested including diet, economic priorities, personal expectations, and health values and beliefs into the refined model. [88]

Figure 5: Refined Model of the Key Components Relating to Oral Health proposed by Brondani et al (2007)



2.2.1.2 Dental Diseases Impacting Oral Health Related Quality of Life:

According to the Global Burden of Disease Study in 2017, oral diseases and conditions affect approximately 3.5 billion people worldwide, with a rising incidence in lower- and middle-income countries due to rapid urbanization and changes in lifestyle. [89-90] Several studies have reported that youth have shown to report lower OHRQoL than did adults. [91-93] This could be due to several factors such as education, negative life experiences, and pain. [94-96] Some researchers have observed that common dental conditions such as caries, gingivitis and periodontitis, edentulism, malocclusion, temporomandibular dysfunction, have no significant impact on an individual's OHRQoL [97-98] while some authors have found an association between poor oral health and OHRQoL. [94,96,99]

i. Dental caries and OHRQoL:

Dental caries is defined as the localized dissolution of the mineralized tissues of the tooth caused by acidic by-products resulting from carbohydrate breakdown or fermentation by

bacteria. [100] In 2017, it was observed that untreated dental decay impacted approximately 2.3 billion people worldwide, making it the most prevalent health condition. [101-102] Untreated tooth decay has been seen to severely affect OHRQoL particularly in children, impacting their routine activities such as eating, sleeping, talking as well as their overall health. [103-104] In a study conducted by Faria et. al that combined untreated dental cavities with clinical outcomes, such as pulpal involvement, ulceration, fistula, and periapical abscess, revealed an increased likelihood of negatively influencing quality OHRQoL. [105]

ii. Periodontal disease and OHRQoL:

Periodontal disease is defined as an inflammatory condition caused by pathogenic microflora present in the oral biofilm or plaque, and therefore affecting the tooth supporting tissues, particularly the gingiva along with the attachment apparatus consisting of the periodontal ligament, alveolar bone and the cementum. [106] Periodontal disease is further classified into gingivitis and periodontitis. Gingivitis is more prevalent, and a milder form of periodontal disease, characterized by redness and inflammation of the gingiva which results in soreness, bleeding gums, and halitosis. [107] Periodontitis is observed when the inflammation extends beyond the gingiva to the attachment apparatus, resulting in loss of the supporting connective tissue and surrounding alveolar bone. This is often characterized by the formation of deep periodontal pockets, gingival recession, mobility of teeth and, eventually, loss of teeth. [108] A systematic review of 37 articles conducted by Buset et, al. demonstrated that there was an association between periodontal disease and OHRQoL, with the quality of life deteriorating further as periodontal disease severity increased. [109] Patients diagnosed with severe periodontitis exhibit higher OHIP-14 scores than do those diagnosed with mild to moderate periodontitis, thereby indicating a worse OHRQoL. Several studies have documented the devastating impact of periodontal disease on the psyche of individuals. With progression of the disease, patients become apprehensive about the symptoms such as tooth mobility and gingival recession, which can result in embarrassment and have a detrimental effect on self-esteem, social interactions and employability. [110-111]

iii. Tooth loss/Edentulism and OHRQoL:

Edentulism is characterized by the absence of natural teeth. An individual may be either partially edentulous (missing a few teeth) or completely edentulous (complete loss of natural teeth). [112] Edentulism is a permanent and irreversible condition and is often considered as the “final marker of disease burden for oral health.” [113] Several studies have identified numerous risk factors in association with complete edentulism such as age, sex, education,

socioeconomic status, access to dental care, dentist to population ratio, as well as insurance coverage. [114-117] In a cross-sectional study conducted by Hewlett et al. amongst 4,724 participants aged 50 years and above, the authors reported that tooth loss is associated with decreased subjective well-being (SWB) and quality of life. [118] Additionally, the number of functioning teeth has been shown to be associated with masticatory ability, thus impacting on OHRQoL and overall well-being. [119] The impact of tooth loss often compels edentulous individuals to modify their dietary habits, leading to reduced satisfaction from meals and compromised nutrient intake. [120] Additionally, subjective well-being amongst the edentulous and elderly populations is linked to self-reported general and systemic health, with individuals in this group often reporting lower satisfaction with their overall health. [121]

iv. Malocclusion and OHRQoL:

Malocclusion is a condition characterized by the deviation of the occlusal relationship from 'ideal' occlusion, which may be perceived as esthetically unsatisfactory. Malocclusion may present as misalignment of individual teeth in each arch or may also present as malrelationship of the dental arches (i.e. improper positioning of the maxilla to the mandible). [122] Previous studies have reported that severe malocclusions such as anterior crowding, spacing in dentition and increased overjet have a deleterious impact on OHRQoL. [123-125] In a cross-sectional study conducted amongst adolescents in New Zealand, females reported lower OHRQoL than did males, except with respect to oral symptoms where males scored higher. This signifies that females prioritize oral health in relation to overall well-being, while males may perceive absence of physical symptoms as equivalent to better OHRQoL. These gender differences highlight the need for tailored interventions in dental care. [126]

v. Temporomandibular Joint Pain and Dysfunction and QoL:

Temporomandibular disorders (TMD) is an umbrella term which comprises several conditions affecting the temporomandibular joint, masticatory muscles and supporting tissues. Therefore, TMD has a dual source of origin: myogenous or muscle-related pain and arthrogenous or joint-related pain. [127] The most frequently observed symptoms of TMD include chronic pain, soreness in the jaw muscles, restricted jaw movement, and noises in the temporomandibular joint (TMJ) during jaw movements. Most of the pain and soreness is localized in the preauricular region and the masticatory muscles. Other manifestations include joint noises such as clicking, popping, grating, or crepitus, as well as jaw movement asymmetry. [128] Chronic pain associated with TMD is often associated with psychological challenges such as anxiety, depression, and stress. This may lead to limited social interactions as well as decreased work

efficiency and significant economic burdens. In severe cases, it may result in unbearable pain or complete incapacitation. [129] Chronic pain adversely affects quality of life, with several patients requiring psychological support alongside medical treatment. These patients also experience sleeping difficulties due to exacerbated pain, and, if not addressed, it may progress to conditions such as sleep apnea and insomnia, further deteriorating the quality of life. [130] It has been reported that patients diagnosed with TMD have poorer OHRQoL than those with periodontal disease and untreated dental decay, as well as neurologic and vascular oral conditions. [131]

2.2.1.3 Oral Health Outcome Measures/ Instruments for Measuring OHRQoL:

The concept of OHRQoL is influenced by three significant perspectives: the condition of the oral cavity itself, oral health governing overall systemic well-being, and the reciprocal effects of general health on OHRQoL. [132] Over the past few decades, there has been great interest in patient-centered care as well as in defining and measuring oral health. Therefore, several tools have been developed to evaluate OHRQoL in individuals.

The most frequently used instruments used in clinical practice and research to evaluate OHRQoL include:

i. Geriatric Oral Health Assessment Index (GOHAI):

The GOHAI instrument was first proposed by Atchinson and Dolan in 1990. The GOHAI measurement tool is comprised of 12 questions across three dimensions: "Physical function," "Psychosocial Function," and "Pain/Discomfort", each of which address the different issues that may affect an individual's OHRQoL. However, despite the three theoretical constructs, the creators of the questionnaire highlight that it ultimately measures only one overarching factor called "self-perception of oral health." [69]

Table 1: Instruments used for measuring OHRQoL

Instrument Name	**Abbreviation**	**Year**	**No. of Items**	**Creators**	**No. of Dimensions Measured**
Prior to 1997					
Social Impact of Dental Disease [133]	SIDD	1986	14	Cushing	5
General Oral Health Assessment Index [69]	GOHAI	1990	12	Atchison & Dolan	3
Dental Impact Profile [134]	DIP	1993	25	Strauss & Hunt	5
Oral Health Impact Profile [7]	OHIP-49	1994	49	Slade & Spencer	7
Oral Health Impact Profile- 14 [135]	OHIP-14	1997	14	Slade	7
Oral Impacts on Daily Performances [79]	OIDP	1997	10	Adulyanon & Sheiham	3
After 1997					
Subjective Oral Health Status Indicators [136]	SOHSI	1999	42	Newman	8
The Oral Health Related Quality of Life Instrument for Dental Hygiene [137]		1999	56	Gadbury-Amyot et al.	7
Orthognathic Quality of Life Questionnaire [138]	OQoLQ	2000	22	Cummingham et al.	4
UK Oral Health Related Quality of Life Measure [139]	OHQoL-UK	2001	16	McGrath & Bedi	3
Oral Health Impact Profile for Edentulous Patients [8]	OHIP-EDENT/OHIP-20	2002	20	Allen & Locker	7
Oral Health Impact Profile- 5 [140]	OHIP-5	2006	5	John et al.	4

ii. Oral Impacts on Daily Performances (OIDP):

The OIDP scale developed by Adulyanon and Sheiham in 1997 evaluates numerous factors which could potentially impact an individual's life. THE OIDP scale consists of 10 questions across three dimensions and has shown benefits when used in population surveys due to its ability to minimize respondent burden. Furthermore, the instrument measures behaviors rather than emotional states, which makes it more efficient for use in research settings. However, there is often a debate about the limited correlation observed between oral health status as defined by professionals and self-assessment when using this tool. [79]

iii. Oral Health Impact Profile (OHIP-49):

The original OHIP-49 tool was proposed by Slade and Spencer in 1994 and provides a comprehensive framework for evaluating OHRQoL in all individuals. The instrument is based upon Locker's conceptual model of oral health which, in turn, was developed from the WHO classification of disease impacts. [77-78] The tool is comprised of seven domains that focus on different aspects of OHRQoL: functional limitations, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. [8] The original OHIP-49 has been adapted a number of times to develop specific versions of the instrument including: OHIP-5, OHIP-14, OHIP-EDENT. Each of the adaptations has been translated into different languages for use cross-culturally.

a. OHIP-5:

The 5-item OHIP instrument for adults is an alternative measurement tool to evaluate OHRQoL and was first developed in Germany. This short instrument includes only 10% of the items in the OHIP-49 but captures 90% of the score information. The OHIP-5 is comprised of four dimensions assessing OHRQoL, with one item for each dimension. Thus, the respondent burden is reduced. [140]

b. OHIP-14:

The OHIP-14 is an abridged version of the original OHIP-49 and has undergone rigorous psychometric assessment across many demographics. [141-142] This concise instrument has been employed in various studies, including clinical trials, where it demonstrated sensitivity to treatment related changes. [143] The OHIP-14 tool has measurement properties on par with the original instrument. [131]

c. OHIP-20/ OHIP-EDENT:

The OHIP-EDENT instrument is designed by Allen and Locker from the original OHIP-49 to evaluate the OHRQoL in edentulous populations. The OHIP-EDENT includes targeted

questions across the same 7 domains as the original questionnaire and aids in accurate assessment of OHRQoL in patients who require rehabilitative treatment. The tool is used to measure OHRQoL both before and after the delivery of the prostheses. [8, 144] The instrument offers a choice of six responses on a Likert scale ranging from 1=Always, 2= Most of the time, 3=Some of the time, 4=Occasionally,5=Rarely, 6=Never. The total OHRQoL score is calculated by summing the scores from all 20 items, providing an overall measure of the individual's perceived OHRQoL.

2.3 Psychometric Properties of an Instrument:

With the rise in evidence-based treatment and advancement in research methodologies, there is great interest in creating measurement instruments such as questionnaires or surveys that play a crucial role in research, guiding clinical practices and in assessing oral health outcomes. [145] Despite the development of various instruments to assess health outcomes, many of these instruments have not been thoroughly validated. [146-147] The measurement tools created should be rooted in established theoretical phenomena and applied in appropriate research and clinical settings, as well as possessing specific characteristics that support their reliability. Therefore, it is necessary for all measurement tools to undergo a validation process to generate accurate results with a minimal chance of error. [148-149] The most important psychometric properties to take into consideration, along with their necessary statistical techniques, include:

2.3.1 Reliability:

Reliability is one of the most critical criteria of an instrument and is defined as the ability of a measurement tool to consistently reproduce identical results of a particular attribute over time, when applied in different populations or settings under similar conditions. Essentially, reliability refers to the “degree of consistency” of an instrument. [150] Testing the reliability of an instrument also aids in identifying errors that could arise from sampling, sociodemographic characteristics of the participants, selection and approval of score raters, as well as the choice of the measurement scale. [151] The most important criteria for evaluating reliability include i. stability, ii. internal consistency and iii. equivalence.

i. Stability:

Stability is defined as the similarity in the generation of results from a measurement instrument when used at two different occasions, thereby indicating a consistency in measurement

repetition. [152] The statistical tests most commonly used to verify the stability of an instrument include:

a. Test-retest Method: This technique involves providing the questionnaire to the same group of individuals on two different occasions and repeating the research. By comparing the outcomes and seeking similarity between results, the reliability (and therefore the stability) can be determined. However, the major limitation of this technique is because memory of previous responses can bias results in subsequent assessments. Often, individuals respond to questions for a second time based on their previous answers, and this results in artificial reliability. This may be improved by increasing the time between the first and the subsequent administrations of the questionnaire.[151] In the test-retest reliability technique, with the same population responding to a questionnaire two or more times, the reliability can be measured using a Pearson's coefficient of correlation. [153]

b. Intraclass correlation coefficient: This modification of Pearson's coefficient was first introduced by Fisher in 1954. [154] The major issue regarding Pearson's coefficient is that it measures association in relation to only two variables and does not provide any information on agreement. [155] On the other hand, it is sensitive to how individuals score items in an instrument. Additionally, it may predict the capability of a research method to identify and quantify consistent discrepancies amongst individuals. [156]

ii. Internal consistency:

Internal consistency evaluates the strength of correlation between the items of a questionnaire and, hence, the consistency in assessing the established characteristic or a construct. [157] Cronbach's alpha coefficient is the most frequently used measure by researchers to evaluate the internal consistency and reliability of an instrument. The main advantage of the Cronbach's alpha coefficient is in its capacity to operate independently: it does not rely on multiple scale administrations or several raters. [158] The Cronbach's alpha highlights the level of covariance between the items of a questionnaire. Therefore, the lower the sum of the variance (of the items), greater is the consistency of the instrument. [159] Cronbach's alpha is calculated as follows:

$$\alpha = \frac{k}{k-1}\left[1 - \frac{\Sigma\sigma_k^2}{\sigma_{Total}^2}\right]$$

where:

k= Number of items in the instrument

$\Sigma\sigma_k^2$= Sum of variance of all items of the instrument

A Cronbach value of at least 0.7 is considered adequate to measure the internal consistency of a tool. Values under 0.7 are considered below optimum and therefore suggest poor internal consistency and weak inter-item correlations within the instrument. Additionally, it should be noted that the value of the Cronbach alpha is dependent on the length of the questionnaire and is seen to increase with a rise in the number of items. The value of Cronbach's alpha is also impacted by the responses of the participants in the study and is therefore representative of reliability in the context of one specific population. Hence, it is essential to assess the reliability of the instrument each time it is administered to new respondents. [151]

iii. Equivalence:

Equivalence refers to the level of agreement between two or more observers when deciphering instrument scores. The commonly used technique to measure equivalence is the "inter-rater reliability test" that requires participation of two or more observers. [160] In this technique, a questionnaire with numerous scales or raters is administered to the same population and then checked for reliability. This test is dependent on thorough training and calibration of the raters, as well as ensuring uniformity of the test application. [161] The inter-rater reliability of a questionnaire can be tested using the kappa statistics. The formula is as follows:

$$K = \frac{P_0 - P_e}{1 - P_e}$$

where,

Po= Proportion of observations in which the two raters agree

Pe= Expected proportion of observations in which the two raters agree by chance

K= Proportion of agreement between the two raters, after factoring out the proportion of agreement by chance.

The kapa value ranges between 0 and 1. A kappa value between 0.41-0.60 is considered sufficient for "fair agreement". However, values below 0.40 are considered to show poor agreement between the raters. Additionally, values above 0.61 and those that are closer to 1 are considered favorable, indicating excellent agreement between the raters. [153]

2.3.2 Validity:

Validity is defined as "the degree to which an instrument truly measures the construct it purports to measure" [162-163] It is important to have a clear definition of what the construct observes. Moreover, the construct must be included in the conceptual model, within a well-described clinical and theoretical framework. It is believed that the psychometric measurement properties are inter-dependent, i.e. if an instrument is not reliable, it is also not valid. [164] The major types of validation types and their techniques are as follows:

i. Content validity:

Content validity is defined as "the degree to which the instrument content adequately reflects the construct that is being measured." [165] This technique is applied at the beginning of the validation process. For measures with multiple items, it is crucial that content validity focuses on assessing whether the items are relevant and cover all aspects of the concept being measured. Additionally, it is important to evaluate whether the items are relevant to the target population being studied and if the items of the instrument adequately cover the construct and its related variables. Content validity of an instrument can be qualitatively evaluated by an independent group of researchers to avoid the risk of bias. Furthermore, a comprehensive description of the outcome measure along with the method of administration should be clearly defined to ensure accuracy. Essentially, this process is aimed at retaining the necessary items and eliminating the redundant questions in an instrument. [164] The Content Validity Ratio (CVR) is calculated using the Lawshe's method:

$$\mathrm{CVR} = \frac{n_e - (\frac{N}{2})}{\frac{N}{2}}$$

where,

ne= Number of expert panel members indicating the items as "necessary"

N= Total number of expert panel members

An additional aspect of content validity, referred to as "face validity", provides an overall assessment of the instrument based on a subjective understanding of the construct being studied. Face validity is conducted with a selected number of respondents to evaluate how they comprehend the items of the questionnaire. This process also includes aspects such as feasibility, structuring, legibility and clarity of language. [166]

ii. Criterion Validity:

Criterion validity is defined as "the degree to which the scores of an instrument are an adequate representation of the gold standard test (i.e. the diagnostic test that confirms whether an individual has a disease or not)." Criterion validity, also referred to as concrete validity, is often used as an alternative approach to interpret test scores. [167] Criterion validity is divided into three types:

a. Predictive Validity: This property aims to assess how well an instrument can accurately predict what it is intended to predict (the concept being studied) theoretically. In this process, first the target test is applied, followed by the gold-standard test. The most suitable technique to evaluate predictive validity of an instrument is by performing a long-term validity study. However, a large sample size is required to collect meaningful data and establish predictive validity.

b. Concurrent Validity: This test is aimed at collecting evidence for predicting other potential outcomes. For example, concurrent validity allows researchers to measure previously recognized constructs by using the test instrument. In this manner, the test can help the researchers to understand if the instrument is able to distinguish between theoretically different constructs.

c. Postdictive Validity: This type of validity compares the scores of the test instrument to the scores from previously developed instruments and assess how closely related the scores are between the two instruments. [149]

iii. Construct Validity:

Construct validity is defined as "the degree to which the scores of a measurement tool are consistent with the hypotheses, e.g., with regard to internal relationships, relationships with scores of other instruments or differences between relevant groups." It is crucial to have a well-defined construct since the entire questionnaire or instrument is designed to evaluate specific concepts related to the research problem being studied. [163] The three types of construct validity are as follows:

a. Structural Validity: This test evaluates the degree to which the scores of an instrument provide an accurate representation of the underlying hypothetical dimension being studied. [163] The structural validity of a tool can be measured using a statistical technique called "factor analysis". An *exploratory* factor analysis is performed when the researchers have a limited understanding of the factorial structure (i.e. number and type of dimensions) in a multi-

item instrument. On the other hand, a *confirmatory* factor analysis is carried out based on previous research findings and to verify predefined hypotheses. [168-169]

b. Hypothesis Testing: This involves formulating hypotheses based on the relationships of the scores of one instrument and how it could potentially relate to scores from another tool evaluating similar or different concepts. A suitable approach for this technique would be developing a series of hypotheses between the test instrument and other related measures, followed by defining the direction and magnitude of the two relationships. [170]

c. Cross-cultural Validity: This is defined as "the degree to which the performance of the items on a translated or culturally adapted instrument is an adequate representation of the performance of items in the original version of the measure." [171] When comparing different sociocultural groups using multi-item instruments, it is important to assume that the items function in a similar manner for all the groups, regardless of their cultural background. This phenomenon is referred to as "factorial invariance." [172] Cross-cultural validity is a qualitative assessment of the instrument involving several steps that are necessary to maintain the quality of psychometric assessment. It is believed that if an instrument is to be used across diverse patient populations, the items must be translated accurately, as well as adapted culturally, to maintain the content validity of an instrument. [173]

2.3.3 Responsiveness:

This psychometric property is defined as "the ability of an instrument to detect a clinical change over time when measuring a specific construct." [171] This psychometric property allows clinicians and researchers to monitor the health of the patient over time. Additionally, it is believed that responsiveness is a measure of longitudinal validity. [174] Responsiveness is evaluated by observing the changes in scores of a test instrument to an established gold standard for change. In the case of continuous variables, coefficient correlations are used to monitor the expected changes; whereas in the case of dichotomous variables, the area under an ROC curve is evaluated (i.e. change vs no change). [175-176]

2.3.4 Interpretability:

Interpretability is defined as "the degree to which a qualitative interpretation (i.e. a clinical or a typically understood inference) can be provided to quantitative scores of a measurement instrument." [171] Clinicians and researchers must emphasize the importance of change in scores and how this may be clinically relevant. This property is vital in every measurement tool

and invaluable for clinicians and researchers, as it explains the significance of scores obtained from the instrument.

2.3.5 Floor and ceiling effects:

The floor or ceiling effect is defined as "the proportion of participants scoring the highest (ceiling) or the lowest (floor) possible score across a specific domain." [177] If floor and ceiling effects are observed, it implies that extreme items are absent in the upper and lower end of the scale, thereby demonstrating limited content validity.

Therefore, the above psychometric properties are necessary to develop a comprehensive instrument that can be applied across diverse patient populations to evaluate health status as well as health-related quality of life.

2.4 Challenges in Measuring OHRQoL:

The primary challenge in measuring OHRQoL construct is because of its evolving and multidimensional nature. The most common concern of researchers is if the dPROM adequately captures the concerns of the individuals completing the questionnaire. Additionally, it is important to understand the patient's perception during administration of the questionnaire- are they evaluating their oral health, OHRQoL or their overall well-being? [178]

Instruments must meet specific criteria, particularly when used in longitudinal studies to assess OHRQoL at both population and individual levels. One of the greatest challenges that researchers may encounter is that measures that are valid and reliable for cross-sectional assessment may not be effective in capturing significant changes over time in longitudinal studies. Therefore, when a new instrument is used in a clinical setting, it is important to evaluate the validity (construct and criterion) as well as the reliability of the instrument, to ensure it is representative of true changes in the patient's OHRQoL. [179-180] Additionally, it is crucial to assess the responsiveness and interpretability of the instrument. Although numerous RCT and experimental studies are using OHRQoL instruments, their responsiveness has not been fully established. It is important to evaluate the instrument's ability to detect and effectively interpret changes over time. [181-182] Widely tested assessment tools were reported as having the best psychometric properties and are also easier to administer, specifically in older individuals. Previous studies have shown that shorter questionnaires seem to have greater

compliance and advantages in the elderly population in comparison to lengthy instruments with specific details. [135, 183]

2.4.1. Inconsistencies in the Validation of the OHIP-EDENT

OHRQoL is particularly difficult to assess in edentulous individuals, whose perceptions and satisfaction of their oral health may differ significantly in comparison to others. Additionally, factors such as individual experiences, coping mechanisms, and societal attitudes towards edentulism could make this evaluation process more complex. The original OHIP-EDENT instrument proposed by Allen and Locker, is widely used to measure the OHRQoL in edentulous individuals. The tool comprises 19 questions, distributed across seven domains.[8]

However, despite its widespread adoption and reliance on the assumption that OHIP-EDENT scores adequately represent the latent construct of OHRQoL, several studies have reported inconsistent findings regarding the questionnaire's structural validity. These inconsistencies raise concerns about whether the tool provides a comprehensive assessment of OHRQoL, which is critical for research and clinical use. Several factors may contribute to these discrepancies. For instance, population differences - individuals from diverse backgrounds potentially perceive OHRQoL differently, leading to varied interpretations of the instrument. Moreover, the use of different lengths of OHIP-EDENT questionnaires across studies, combined with different approaches to data analysis, has contributed to inconsistent results. Smaller sample sizes in some studies may also have introduced sampling errors, further contributing to the inconsistency in findings. Finally, the omission of certain psychosocial elements or the potential overlap between domains within the questionnaire may further compromise its validity, suggesting a need for further refinement and validation of OHIP-EDENT. The table below presents the different factor structures reported in the literature regarding OHIP-EDENT. These variations raise concerns about the structural validity of the tool, as the factors underlying its design may not be consistently interpreted or supported across different studies

Table 2: Factor structures observed for the OHIP-EDENT in the current literature

Author	**Year**	**Population**	**Sample Size**	**Treatment Provided**	**OHIP_EDENT Version Used**	**Factor Structure Observed**
Souza et al. [184]	2010	Brazilian edentulous individuals	103	a. N=65 (Conventional dentures) b. N= 13 (Conventional maxillary dentures opposing to mandibular implant-retained overdentures) c. N= 25 (Mandibular or maxillary fixed implant-supported CDs as opposed to conventional CDs or other similar fixed dentures	Brazilian OHIP-EDENT (19 items)	a. Factor 1: Masticatory Related Complaints b. Factor 2: Psychological Discomfort and Disability c. Factor 3: Social Disability d. Factor 4: Oral Pain and Discomfort
Montero et al. [185]	2012	Spanish edentulous population	41	a. N=21 (Mandibular overdentures and Maxillary complete denture) b. N=20 (Conventional Dentures)	OHIP-20sp	a. Factor 1: Disability b. Factor 2: Functional comfort, c. Factor 3: Psychosocial impact d. Factor 4: Pain-discomfort e. Factor 5: Functional limitations
He et al. [186]	2015	Chinese edentulous individuals	162	c. Conventional Complete Dentures	OHIP-EDENT-C (22 items)	"EFA extracted five factors, including denture-specific aspect associated with psychological, physical and social characteristics."

Possebon et al. [187]	2018	Brazilian edentulous individuals	54	Conventional Complete Dentures	OHIP-19	a. Factor 1: Physical Impact b. Factor 2: Psychological Impact c. Factor 3: Social Impact
Shrestha et al. [188]	2018	Nepalese edentulous individuals	88	Conventional Complete Dentures	OHIP-EDENT-N (19 items)	"Five factors were identified and extracted using the EFA, including denture-specific aspects associated with psychological, physical, and social characteristics."
Bural et al. [189]	2021	Turkish edentulous individuals	104	Conventional Complete Dentures	OHIP-EDENT-T (19 items)	a. Factor 1: Physical Impact b. Factor 2: Psychological Impact c. Factor 3: Social Impact
Elenčevski et al. [190]	2021	North Macedonian edentulous individuals	109	Conventional Complete Dentures	OHIP-EDENT-MAC (19 items)	a. Factor 1: Masticatory Function b. Factor 2: Social Impact c. Factor 3: Pain d. Factor 4: Psychological Impact
Čelebić et al. [191]	2021	Crotian (N=95) Serbian (N= 177) edentulous individuals	272	Croatia: N= 83 (Conventional Complete Dentures), N= 12 (CDs +RPD) Serbia: All Conventional Complete Dentures	OHIP-EDENT-CRO, OHIP-EDENT-SERB (both 19 items)	"The four factors extracted in this study could not be interpreted in a clear manner. According to the content of the items, the dimensions could be Function, Pain, Comfort and Psychosocial Impact."

3. RATIONALE

Edentulism significantly impacts an individual's quality of life, including functional abilities, psychological health, and social well-being. The OHIP-EDENT is a valuable tool that is used to measure the OHRQoL in edentulous individuals. This instrument is used in both clinical practice and research settings to assess the impact of edentulism, observe changes over time, and evaluate the effectiveness of interventions aimed at improving OHRQoL in edentate individuals. The OHIP-EDENT tool, which is a shortened version of the full OHIP-49 questionnaire, consists of 19 items across seven subscales (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap). While this version of the OHIP-EDENT has been widely used, some studies have suggested that fewer domains (three or four) in comparison to the seven-domain framework of is sufficient to effectively measure OHRQoL in edentulous individuals. However, further validation of these alternative frameworks across different populations is necessary to establish the instrument's validity, accuracy and robustness. My study addresses this need by using a rigorous methodological approach. This project includes data from 2 countries (Canada and the US), to improve the generalizability and robustness of the OHIP-EDENT instrument across different populations. This binational approach provides a broader perspective into the reliability of the OHIP-EDENT. Additionally, my research work goes a step further by assessing a previously established factor structure from a Brazilian population and applying it to the Canadian cohort. This allows us to evaluate the OHIP-EDENT's cross-cultural applicability whilst providing an insight into universal aspects of OHRQoL so that we can better address the unique challenges faced by edentulous individuals.

4. AIMS AND OBJECTIVES

The overarching aim of this project is to estimate the extent to which the OHIP-EDENT accurately reflects OHRQoL by using data from two studies and evaluating the optimal factor structure which could potentially improve OHIP-EDENT's validity. Specifically, this project aims to determine whether a shorter version of the OHIP-EDENT can effectively measure the same OHRQoL construct.

Objectives:

i. To identify the underlying factor structure of the OHIP-EDENT questionnaire using an exploratory factor analysis (EFA) technique on data from a US population.

ii. To apply a hypothesis-testing confirmatory factor analysis technique on data from a Canadian population to determine the relevant number of factors that adequately represents the OHRQoL construct measured by OHIP-EDENT.

iii. To evaluate the cross-cultural applicability of the OHIP-EDENT by testing an alternative factor structure proposed in the literature on the Canadian population.

5. METHODOLOGY AND RESULTS: MANUSCRIPT

Preface:

OHRQoL specifically focuses on how oral health conditions and related treatments can impact an individual's overall well-being. It considers factors such as pain, discomfort, functional limitations, psychological well-being, social interactions, and self-esteem related to oral health. Instruments such as the OHIP-EDENT have been crucial in assessing OHRQoL in edentulous populations. This chapter includes the manuscript from the study which aims to establish the most relevant factor structure to explain the multidimensional concept of OHRQoL. Through a rigorous methodological approach, we have sought to identify the key dimensions which influence OHRQoL in the North American edentulous population. The insights gained from this research have the potential to guide clinicians to provide holistic care whilst empowering patients to advocate for their oral health needs.

Title: Unveiling the latent structure of the OHIP-EDENT Instrument: A Comparative Evaluation of the three-factor vs. four-factor Models in a binational context

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Abstract

Background: Oral Health Related Quality of Life (OHRQoL) plays a fundamental role in the overall well-being. The OHIP-EDENT inventory, used to evaluate OHRQoL in edentulous individuals, follows a 7-factor solution. While this original version was initially believed to accurately capture the latent construct of OHRQoL, multiple studies have challenged this, demonstrating that alternative 3- and 4-factor analytic approaches are also sufficient.

Objective: To assess the inter-relationship between the OHIP-EDENT items and clarify its structural validity, addressing the potential for shorter factor approaches to effectively measure OHRQoL in edentulous individuals.

Methods: We used baseline data from edentulous participants from two studies, a randomized clinical trial (n=255) conducted in Canada and a quasi-experimental study conducted in the USA (n=165). A total of 420 participants completed the OHIP-EDENT, which consists of 20 questions addressing individual's perceptions regarding the functional, psychological, and social implications of edentulism. Sampling adequacy was verified by the Kaiser-Meyer-Olkin and Bartlett tests. Subsequently, we applied Exploratory Factor Analysis (EFA) on the US study data to identify the latent constructs (factors). After identifying the three-factor structure from the EFA, we employed a Confirmatory Factor Analysis (CFA) on the Canadian sample to validate the hypothesized model. EFA and CFA were performed on separate datasets to enhance the stability and generalizability of the identified factor structure.

Results: The EFA unveiled a three-factor configuration, highlighting the latent factor structure of the OHIP-EDENT. After determining the internal consistency (Cronbach's alpha = 0.946), the model fit was validated on the Canadian cohort by implementing a three-factor CFA approach. Additionally, a four-factor CFA test was performed on the Canadian cohort to compare the 2 models. The three-factor model identified "Functional and Psychological Well-Being," "Social Impact," and "Oral Pain and Discomfort" as constructs, whereas the hypothetical four-factor model included the "Masticatory-Related Complaints" construct.

Conclusion: Our results support the idea that a shorter version of the OHIP-EDENT questionnaire measures the same dimensions as the 7-factor solution for the OHIP-EDENT.

Key words: Quality of Life, Oral Health, Validation, Factor Analysis

Introduction:

Edentulism, the absence of natural teeth, is a permanent and irreversible condition and is often considered the "final marker of disease burden" for oral health. It may manifest as partial edentulism (missing a few teeth in the oral cavity) or complete edentulism (complete loss of natural teeth in the oral cavity).[1-2] Despite the significant decline in edentulism over the last few decades, tooth loss remains a major concern, especially for the elderly populations.[7] In Canada, the prevalence of edentulism amongst adults between 60-79 years of age varied between 6.4% and 21.7%.[8] There is a substantial difference in the prevalence across Canadian provinces, with Quebec at 14% and the Northwest Territories at 5%. These discrepancies are influenced by factors such as smoking and access to fluoridated water.[9] In the United States, Slade et al. (2014) found that 4.9% of a sample of 432,519 adults above 15 years of age was edentulous.[10] Several studies have identified numerous risk factors for complete edentulism, such as age, sex, education, socioeconomic status, access to dental care, dentist to population ratio, and insurance coverage.[3-6]

Edentulism has a significant impact on the overall well-being of an individual. For instance, a cross-sectional study amongst 4,724 Ghanaians aged 50 years and above found that tooth loss is associated with decreased subjective well-being and quality of life (QoL).[11] Additionally, the number of functioning teeth has been associated with masticatory capacity and oral health related quality of life (OHRQoL).[12] Edentulism often compels individuals to modify their dietary habits, leading to reduced satisfaction with meals and compromised nutrient intake.[13] Furthermore, reported well-being amongst the edentulous and elderly population is linked to self-reported general and systemic health, with individuals in this group often reporting lower satisfaction with their overall health.[14]

With the increase in awareness of patient-centered and holistic care, patient reported outcomes (PROs) have become an important tool to assess individual perceptions of clinical outcomes, as well as behavior change.[15] The concept of PROs focuses on the possibility for individuals to express their perspectives on the symptoms of disease, associated treatment, and their interactions with the healthcare system.[16] In doing so, they provide valuable insights into the condition, its impact, and how it affects daily functioning. This enables an individual to have greater autonomy in their treatment should they desire to be an active participant in their care.

Dental PROs are different in comparison to those observed in the field of medicine. Instruments that capture these are referred to as Dental Patient Reported Outcome Measures (dPROMS).[17]

Patients generally express concerns that are related to specific aspects of their oral health, in particular: a. dental and orofacial pain, b. functional limitations with respect to jaw movement, c. concerns about compromised dental and orofacial esthetics, d. broader psychosocial concerns related to oral diseases. These 4 constructs can be collectively grouped under the concept of Oral Health Related Quality of Life (OHRQoL).[18] Since most dental diseases have little relevance with respect to mortality, the focus for dental patients shifts towards understanding the impact of oral diseases on an individual's daily routine. This emphasis is particularly pronounced given the chronic nature of most dental conditions, such as edentulism.[19]

There are several instruments available that measure different dental and oral health symptoms. One such example is the Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT). The OHIP-EDENT instrument, designed by Allen and Locker from the original OHIP-49 to assess OHRQoL in edentulous populations, consists of 20 items with questions in 7 subscales: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap.[20] While the Allen and Locker scale has been widely used and the structural validity of the 7 domains confirmed in several studies, some authors argue that similar results can be achieved with just 3 or 4 domains. This raises the question of whether a shorter version of the scale could effectively measure the same construct. To address this, we evaluated the inter-relationship between the OHIP-EDENT items and clarified its structural validity, by using baseline data from two studies on edentulous patients.

Methodology:

i. Study design, participants and OHIP-EDENT data collection:

This study is a secondary data analysis using baseline data from a randomized controlled clinical trial (RCT) and a quasi-experimental study in which the participants were provided with clinically acceptable dentures. Baseline data provide a starting point that is not affected by an intervention. Therefore, it allows us to determine a valid and reliable model that precisely represents the constructs of interest.

a. Study 1: McGill University, Canada

The data from the first study was obtained from a RCT assessing the effects of mandibular implant overdentures on the nutritional status of an edentate elderly population.[24] This RCT, conducted at McGill University, Montreal, Canada, included 255 completely edentulous men and women aged 65 years or older, with a minimum edentulous period of 5 years. A computer-generated permuted block scheme was used to stratify participants by sex and type 2 diabetes status. Participants were then randomly assigned to receive either traditional or implant-retained mandibular complete dentures and were followed for up to 12 months, with a focus on nutritional biomarkers and diet.

b. Study 2: University of Texas Health Sciences Centre at San Antonio, United States

This study was fully described elsewhere.[25] Briefly, it was conducted from 2007 to 2012, at the University of Texas Health Science Centre at San Antonio, USA. It included a total of 165 edentulous patients 25 years or older, with or without type 2 diabetes mellitus, who needed treatment with two implants in the mandibular anterior region to retain a complete overdenture.

Both above-mentioned studies used the OHIP-EDENT instrument to evaluate OHRQoL before and after prosthetic rehabilitative treatment. OHIP-EDENT is specific to edentulous patients and includes questions pertaining to masticatory capacity, pleasure in eating, level of comfort and assuredness while wearing the prosthesis, and relationship problems, among others. The items are rated on six-point Likert scales (‘‘never’’ = 1, ‘‘rarely’’ = 2, ‘‘occasionally’’ = 3, ‘‘often’’ = 4, ‘‘very often’’ = 5 or ‘‘all of the time’’ = 6). The total range of OHIP-EDENT is between 20–120 points. Therefore, lower scores indicate better oral health-related quality of life.[26] Participants who had missing responses for more than 5 items of the questionnaire were excluded from the analysis to not compromise the accurate interpretation of the OHIP-EDENT structure.[27]

ii. Statistical Analysis:

To ensure that the OHIP-EDENT tool is a valid measure of OHRQoL, the items of the questionnaire must represent actual patient perception of oral health, i.e. structural validity. An important aspect of establishing structural validity is the use of statistical techniques such as exploratory and confirmatory factor analysis. The exploratory factor analysis (EFA) is performed when the researchers have a limited understanding of the factorial structure (i.e. number and type of dimensions) in a multi-item instrument. Additionally, a confirmatory factor analysis (CFA) is carried out based on previous research findings and to verify predefined hypotheses.[21-22]

We applied the EFA statistical technique, followed by a CFA method, to evaluate the number of dimensions of the OHIP-EDENT Questionnaire. Furthermore, our study involves an additional approach to identify the cross-cultural applicability of the OHIP-EDENT instrument using a factor structure from previously published literature.[23] Through this method, we aim to determine the most appropriate factor structure of the OHIP-EDENT to adequately represent OHRQoL in edentulous patients

To perform the factor analysis, we used baseline data from the two studies to ensure robustness, reliability, and generalizability of our findings. The statistical analysis is performed on The R Project for Statistical Computing Version 4.3.2. The statistical analyses are divided into two aspects as follows:

a. To identify the underlying factor structure of the OHIP-EDENT by analysing the responses of the US population, followed by testing the hypothesis in the Canadian population:
   - After excluding participants with many missing responses, a total of 154 participants were included for the initial EFA analysis. Prior to performing the EFA, two preliminary tests were conducted: (i) Kaiser-Meyer Olkin for sampling adequacy, and (ii) Bartlett's Test for the correlation between the OHIP-EDENT items. Dimensionality was measured using the ratio of first-to-second eigenvalue, Cattell's scree plot and Horn's parallel analysis.[28-29] A first-to-second eigenvalue ratio greater than four indicates unidimensionality.[30] Horn's parallel analysis compares the observed eigenvalues to random eigenvalues, maintaining the number of observed eigenvalues that surpass the simulated eigenvalues. These criteria provide us with data-driven knowledge on the number of factors to extract thereby improving the reliability of the EFA results. The factor extraction was done using the Principal Axis Factoring (PAF) Technique, along with the promax oblique rotation technique, since the factor/construct is related to other factors to some extent in the OHIP-EDENT questionnaire. Factor solutions with loadings greater 0.40 were considered as significant.[31] To evaluate the internal reliability of the model, the Cronbach alpha is presented for each factor in the final solution. Values greater than 0.7 indicate a factor structure with good internal consistency to proceed for the CFA.[32]

   - After identifying the appropriate factor structure through the EFA, this hypothetical model was tested on the data of the Canadian cohort using the CFA technique. A path diagram was constructed to represent the factored model. To prioritize hypothesis testing,

the Unweighted Least Squares Estimation Method was used due to the ordinal nature of the data from OHIP-EDENT responses. The Root Mean Square Error of Approximation (RMSEA), Tucker-Lewis Index (TLI) and Comparative Fit Index (CFI) have been included in this analysis. Commonly used guidelines for adequate model fit include RMSEA values ≤ 0.06, and CFI, TLI ≥ 0.95.[33]

b. Cross-cultural applicability of the OHIP-EDENT instrument:

A previously published four-factor EFA solution observed in a Brazilian population was applied to the current Canadian data to evaluate the most appropriate factor structure that would adequately represent OHRQoL in edentulous patients.[23] The same CFA parameter settings mentioned above were applied to this analysis. A final comparison of the fit indices was done to determine the most suitable factor structure.

Results:

i. Socio-demographic characteristics of the population:

Table 1 presents the sociodemographic characteristics of the participants from both the studies (N=420). With respect to the Canadian sample (N=255), about 55.3% (n=141) of the participants were female with 51.4% (n=131) being above the mean age of 68. Approximately 41.6% (n=118) of the Canadian cohort have completed secondary education and 81.6% (n=208) of the participants were retired during the time of the study. In the US sample (N=165), 52.7% (n=87) of the participants were female and 66.1% (n=109) were below the mean age of 68 years.

ii. EFA of the OHIP-EDENT (based on US population):

Of the 20 possible factors, only three were considered relevant for this study. The eigenvalues of the correlation matrix implied a dominant general factor. The first eigenvalue of 13.069 and the second eigenvalue of 1.169 yielded a ratio of 10.92, confirming unidimensionality. The third eigenvalue was 1.108. Additionally, the scree plot showed a steep drop from the first to second factor, emphasizing on a strong general factor. However, the Horn's parallel analysis

test confirmed the retention of three factors to perform the EFA on the US population (Figure 1).

Table 2 illustrates the eigenvalues along with the proportion variance. Prior to rotation, the first eigenvalue explained 64.1% of variance within the instrument. However, after applying the promax oblique rotation and PAF technique, the variance within the instrument was redistributed among the three factors. Both the models explain 73% of variance.

A total of 13 items of the OHIP-EDENT questionnaire loaded on to the first factor, "Functional and Psychological Well-being". The questions mostly focused on masticatory complaints, unsatisfactory diet as well as issues with self-esteem due to absence of teeth. A second factor "Social Impact" contained 5 items which were related to social impairment. Lastly, the third factor "Oral Pain and Discomfort" contained two items, focusing on the presence of sore spots and pain in the mouth (Table 3).

The Cronbach alpha of the entire instrument is 0.97, 0.97 for "Functional and Psychological Discomfort", 0.86 for "Social Disability" and 0.94 for "Oral Pain and Discomfort".

iii. CFA of the OHIP-EDENT (based on Canadian population):

CFA was used to validate the above hypothetical three-factor EFA model. The RMSEA (0.043), the CFI (0.995) and the TLI (0.994) fit indices reveal that the model is an excellent fit for the data. Figure 2 explains the underlying relationships between the latent construct (three factors) and the observed indicators (i.e. items of the instrument). Furthermore, we can assess the extent of correlation amongst the three factors.

iv. Cross-cultural applicability of the OHIP-EDENT (factor structure from previously published literature applied to Canadian population):

de Souza et al. recognized a four-factor EFA model in the OHIP-EDENT instrument that accurately represents the construct of OHRQoL in edentulous patients. The four constructs include: "Masticatory-related complaints, Psychological discomfort and disability, Social disability, Oral pain and discomfort."[23] Based on the factor loadings (as observed in the published literature), we conducted a second CFA test to identify the most appropriate factor structure of the OHIP-EDENT. The Root Mean Square Error of Approximation (0.037), the

CFI (0.996) and the TLI (0.996) demonstrate that the four-factor solution observed in the Brazilian population, appears to be an excellent fit for the Canadian population too. Figure 3 explains the relationships observed between the latent construct (four factors) and the observed indicators (i.e. items of the instrument).

v. Comparison of the two CFA models:

Both the three-factor and four-factor CFA models exhibit excellent fit indices, with the RMSEA, CFI, and TLI values indicating a very good fit in both cases. However, the four-factor model stands out due to marginally better fit indices.

Discussion:

Our secondary analysis of data from edentulous individuals in the US and Canada confirmed that both the three and four-factor solutions adequately represent OHRQoL in edentulous populations. By performing an initial EFA, we were able to identify three factors that are relevant to edentulous individuals from the US study. These three factors were identified as "Functional and Psychological Well-being", "Social Impact" and "Oral Pain and Discomfort". These findings contrast with the OHIP-EDENT (modified from the original OHIP-49) that include the seven dimensions: *Functional Limitations, Physical Pain, Psychological Discomfort, Physical Disability, Psychological Disability, Social Disability and Handicap.*[20] Several studies have identified various models with fewer factors that explain the multidimensional concept of OHRQoL. Our findings of a three-factor model for the OHIP-EDENT align with those of Possebon et al.[34] We believe these three factors serve as fundamental components of how edentulous individuals perceive their oral health, as well as for measuring OHRQoL.

The first factor, labeled "Functional and Psychological Well-being," included the first 15 questions of the instrument, except questions 4 and 6. This factor encompassed questions from the original constructs: Functional Limitation (3 questions), Physical Pain (2 questions), Psychological Discomfort (2 questions), Physical Disability (3 questions), and Psychological Disability (2 questions). The "Functional and Psychological Well-being" dimension had the highest eigenvalue amongst the three constructs identified through the EFA on the US population. This confirms that most of the variance of the instrument is related to the presence

of physical and psychological symptoms. Furthermore, it is noteworthy that no previous studies have shown a combination of functional and psychological dimensions into a single factor, thereby indicating that there is a strong correlation between the two domains. Additionally, we can infer that individuals experiencing functional limitations are likely to report psychological discomfort and vice versa. In various cultures, tooth loss is seen as a natural process associated with ageing. Although people may physically adapt to wearing removable or fixed prostheses, they often experience emotional challenges such as anxiety, depression, and decreased self-esteem, thereby negatively impacting their overall QoL.[35] With a decline in psychological well-being, these individuals often experience social isolation and are uncomfortable engaging in social interactions with friends or family, thereby resulting in further emotional distress. A study by Heydecke et al. observed that edentulism significantly impacted the social lives of Canadian adults. However, this issue can be mitigated through the provision of conventional dentures or implant retained overdentures.[36] We observed a distinct "Social Impact" factor in our study, which comprised the last 5 questions of the OHIP-EDENT instrument: "Social disability" (3 questions) and "Handicap" (2 questions). While our findings align with previous studies evaluating OHRQoL in edentulous patients using the OHIP-EDENT tool[23-34], they differ from those using the OHIP-14 instrument, which identified a single "psychosocial" domain, suggesting that the various dimensions of OHRQoL are closely interconnected and significantly influence an individual's overall well-being.[37] Finally, the third construct "Oral Pain and Discomfort" comprised of questions 4 and 6 from the original OHIP-EDENT instrument. The identification of this separate factor implies that oral pain and discomfort is more than just a subcomponent of larger functional and psychosocial constructs. In reality, it highlights an influential aspect of oral health that requires specific consideration in both research and clinical practice, as it directly impacts the patient's overall well-being. De Souza et al. discovered that the "Physical Impact" domain can be further classified into "Masticatory complaints" and "Oral Pain" to better represent how physical impairments in oral health affect daily functioning and patient comfort.[23]

By performing a CFA on the Canadian cohort using the three-factor model, we found that "Functional and Psychological Well-Being," "Social Impact," and "Oral Pain and Discomfort" are sufficient to adequately represent OHRQoL in edentulous individuals. However, our study goes a step further by evaluating the applicability of the four-factor model previously identified in the Brazilian population, discovering that it offers a more detailed and comprehensive understanding of OHRQoL in the North American context as well.[23] By validating the four-

factor model on the Canadian population, we confirm its robustness and generalizability across different cultural settings. Incorporating a specific "Masticatory-related complaints" factor into the model, we confirmed the OHIP-EDENT's ability to precisely capture patient experiences, and therefore its accuracy and relevance in diverse populations.

The strength of our study lies in its robust methodology and comprehensive approach. Our findings contribute to an improved understanding of OHRQoL and perceived oral health across different cultural contexts. The inclusion of two samples from different populations, as well as the use of a 4-domain framework from a third population (Brazil), enforces the external validity/generalizability of our results. This statement can be reinforced by statistics, which yielded highly favorable results for the tested models. These aspects lead us to recommend that the results are directly generalizable to (at least) edentulous populations of the Americas. This enhances the credibility of the OHIP-EDENT as a measurement tool across different populations and diverse cultural settings. Through this structural validation of the OHIP-EDENT tool, researchers and clinicians can identify the major concerns of edentulous populations from their own perspectives and create patient-centric treatment plans to address both oral and overall well-being of an individual. A limitation of our study would be the variations in cultural norms, beliefs, and healthcare systems between countries may impact the applicability of findings, emphasizing the need for caution when interpreting results across populations. Researchers should consider whether merging of older domains and creating new constructs, such as the approach in our study (e.g. functional and psychological aspects of the original 7-factor model combined into a single domain) will be applicable and valid across different populations. Further research is needed to validate these models in diverse demographic groups to determine their robustness and generalizability.

Conclusion:

Future studies measuring the OHRQoL in edentulous individuals using the OHIP-EDENT could focus on a simpler model, when compared to the 7-domain traditional framework. These shortened versions combining multiple theoretical constructs are clinically sound, exhibit good face and content validity, as well as address the major concerns of both patients and clinicians. By concentrating more items within fewer domains, these models have shown enhanced statistical properties and provide a more streamlined approach to measure OHRQoL.

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Tables and Figures:

Table 1: Sociodemographic Information of Participants from Canada and US

	Canada (N=255)	US(N=155)
Age • Older Patient (>68 Years) • Younger Patient (<= 68 Years)	• 131 (51.4%) • 124 (48.6%)	• 56 (33.9%) • 109 (66.1%)
Sex • Female • Male	• 141 (55.3%) • 114 (44.7%)	• 87 (52.7%) • 78 (47.3%)
Treatment Provided • Conventional Complete Dentures • Conventional Maxillary Denture with Mandibular Implant Overdentures	• 128 • 127	• N/A • 165

Table 2: Eigenvalues of the EFA on the US Population

		Unrotated Solution			Rotated Solution		
	Eigenvalues	Sum Sq. Loadings	Proportion variance	Cumulative variance	Sum Sq. Loadings	Proportion variance	Cumulative variance
Factor 1	13.068	12.81	0.87	0.87	7.90	0.40	0.40
Factor 2	1.196	0.93	0.064	0.934	4.85	0.24	0.64
Factor 3	1.107	1.94	0.058	0.992	1.84	0.09	0.73

Table 3: CFA Fit Indices of the three-factor model on Canadian Population

Index	Value
Comparative Fit Index (CFI)	0.995
Tucker-Lewis Index (TLI)	0.995
Bentler-Bonett Non-normed Fit Index (NNFI)	0.995
Bentler-Bonett Normed Fit Index (NFI)	0.985
Parsimony Normed Fit Index (PNFI)	0.865
Bollen's Relative Fit Index (RFI)	0.983
Bollen's Incremental Fit Index (IFI)	0.995
Root mean square error of approximation (RMSEA)	0.042
RMSEA 90% CI lower bound	0.029
RMSEA 90% CI upper bound	0.053
RMSEA p-value	0.874

Table 4: CFA Fit Indices of the four-factor model (seen in Brazilian population) on Canadian Population

Index	Value
Comparative Fit Index (CFI)	0.997
Tucker-Lewis Index (TLI)	0.997
Bentler-Bonett Non-normed Fit Index (NNFI)	0.997
Bentler-Bonett Normed Fit Index (NFI)	0.987
Parsimony Normed Fit Index (PNFI)	0.852
Bollen's Relative Fit Index (RFI)	0.984
Bollen's Incremental Fit Index (IFI)	0.997
Relative Noncentrality Index (RNI)	0.997
Root mean square error of approximation (RMSEA)	0.034
RMSEA 90% CI lower bound	0.018
RMSEA 90% CI upper bound	0.046
RMSEA p-value	0.986

Figure 1: Scree Plot with Parallel Analysis for EFA

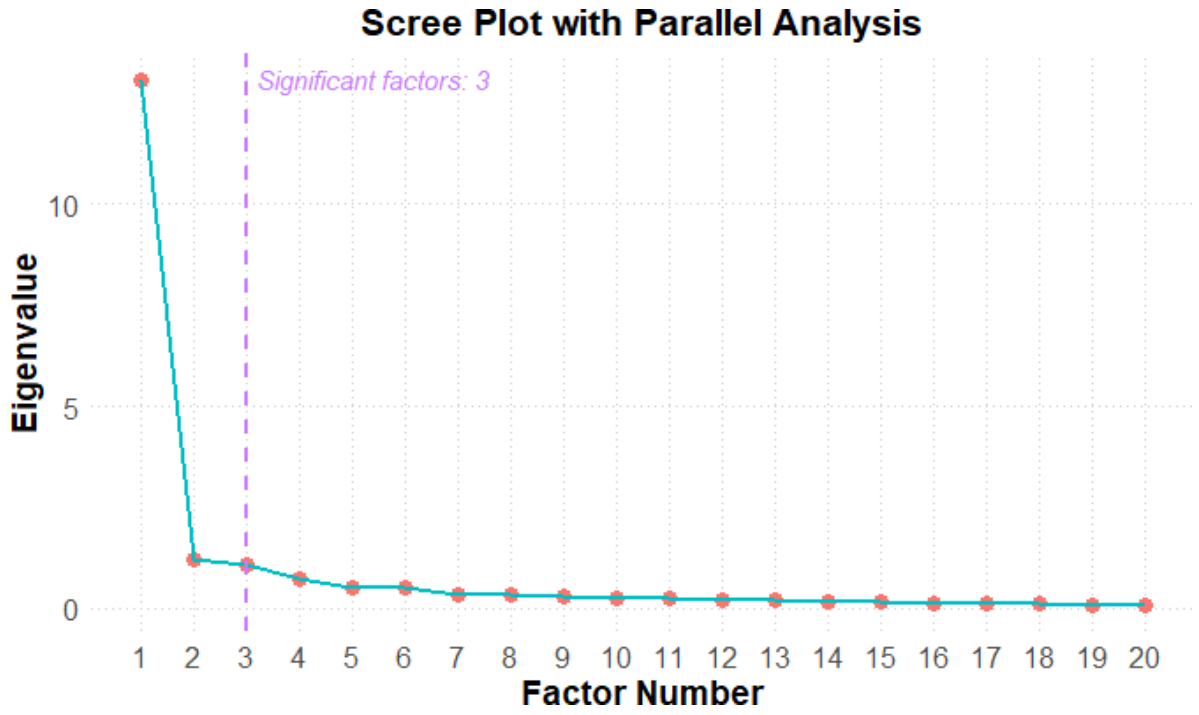


Figure 2: Path Diagram for the three-factor CFA Model

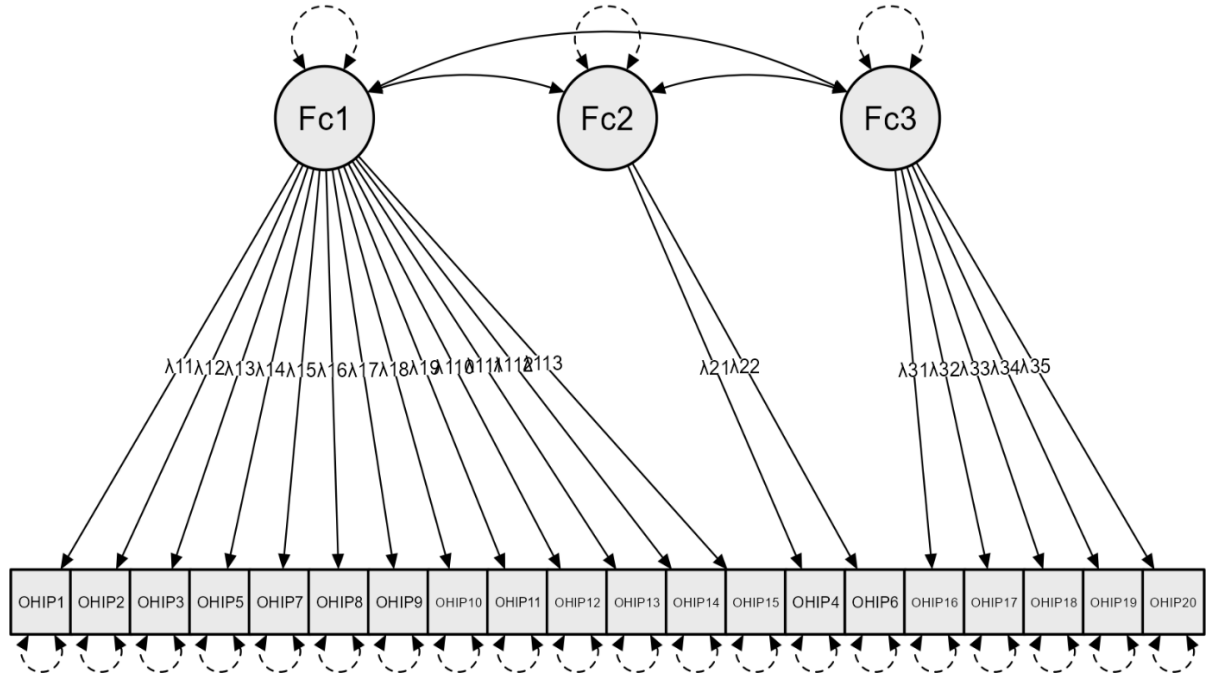
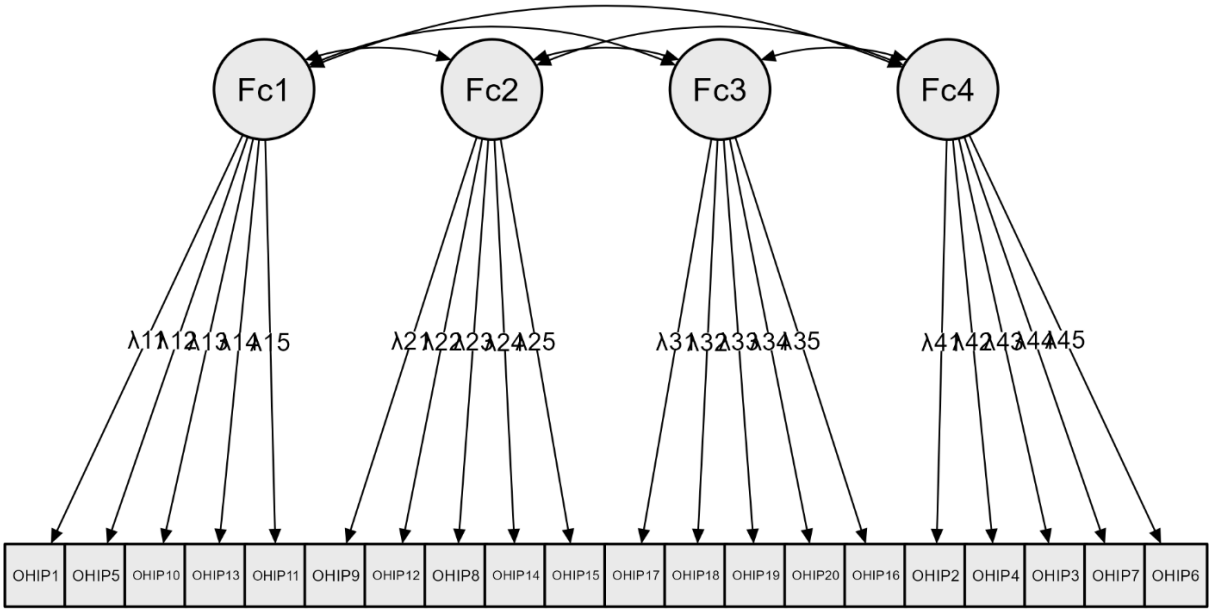


Figure 3: Path Diagram for the four-factor CFA model



6. DISCUSSION

This chapter provides an overview of the key findings from this study. It begins with a discussion of the main results, highlighting their relevance to existing knowledge gaps in the literature on OHRQoL in edentulous individuals. The section then addresses the study's methodological strengths, including validating the OHIP-EDENT instrument through EFA and CFA using two datasets. The findings aim to help both clinicians and researchers understand how different factors, such as functional well-being, social impact, and oral discomfort, contribute to the overall quality of life in edentulous populations. Following this, limitations are considered, and the chapter concludes with directions for future research, practical applications, and knowledge translation.

6.1 Summary of Findings:

By performing a rigorous validation of the OHIP-EDENT instrument, this study identified the key dimensions which effectively measure OHRQoL in edentate individuals. The results align with previous research indicating that fewer domains may be just as effective in capturing OHRQoL in edentulous populations as the traditional seven domains proposed by Allen and Locker. By implementing the factor analysis technique on the OHIP-EDENT instrument, we attempted to simplify the existing intricate relationships and identify the key dimensions that contribute to OHRQoL amongst edentulous individuals. The findings from the current study suggest that a model focusing on three or even four domains is sufficient to capture the essence of OHRQoL in this population.

The initial EFA on the US population suggested a three-factor model to evaluate OHRQoL in edentulous patients. The dimensions "Functional and Psychological Well-Being," "Social Impact," and "Physical Discomfort" capture the relationship between physical function, emotional well-being, and social interactions. The three-factor model observed in the US population is consistent with previous research in Brazilian and Turkish populations, thereby highlighting that these constructs are essential for understanding how edentulous individuals perceive their oral health as well as for effectively measuring OHRQoL. [187, 189] The combination of the functional and psychological aspects of the OHIP-EDENT into a single construct is a crucial finding not observed in previous studies, highlighting the link between physical function and psychological distress. For example, a cross-sectional study conducted in Southern India which evaluated the masticatory efficiency, OHRQoL and depressive symptoms showed that those individuals who became completely edentate before the age of

55, especially females and participants not using complete dentures, reported greater depression. Additionally, reduced masticatory capacity was identified as a risk factor for psychological distress, with participants having poor quality dentures further contributing to lower OHRQoL. [192] Several studies have reported that poor oral health related quality of life is associated with increased feelings of loneliness and social isolation amongst elders. Moreover, psychological distress further contributes to social isolation, resulting in a decline in the overall well-being of these individuals. [193-194] We have identified "Social Impact" as the second factor which significantly impacts the OHRQoL in edentate individuals. Our findings of a distinct factor related to the social impact of edentulism aligns with previous studies. [184, 187, 189, 190]. Despite the diverse demographic, cultural and geographic settings in various studies, edentate individuals are faced with recurring challenges such as social isolation, loneliness and psychological distress. These insights suggest that clinicians should consider a more holistic approach to oral health by utilizing validated instruments such as the OHIP-EDENT. This would promote patient-centered care by enabling tailored interventions that address the functional and psychological needs of edentulous individuals, ultimately improving their overall well-being. Lastly, we recognized a specific "Oral Pain and Discomfort" construct which influences OHRQoL in this population. Freitas et al have reported the presence of oral lesions, such as denture stomatitis, inflammatory hyperplasia, traumatic ulcers, and angular cheilitis with improper use of complete dentures in edentulous individuals [195]. Additionally, a study conducted amongst the elderly population of Nottinghamshire, UK revealed that 74% of the participants were wearing ill-fitting dentures for over a decade. As a result, 40% of the participants reported pain and discomfort under the dentures, significantly impacting their masticatory abilities. [196]

Through the CFA approach, we have confirmed that the three factors identified in the U.S. population are also sufficient to describe OHRQoL in the Canadian population, further validating the robustness of our findings. Our project goes a step further by assessing the cross-cultural applicability of the 4-factor solution of the OHIP-EDENT previously observed in a Brazilian edentulous population. [184] The fourth factor identified by Souza et al. focuses on "Masticatory Related Complaints". By including an additional dimension to the Canadian edentate population, we improve our understanding of how specific oral health issues can impact the experiences of these individuals.

The use of validated instruments such as the OHIP-EDENT within clinical settings is necessary to enhance care delivery and promote patient-centered care for edentulous

individuals. These measurement instruments allow the clinicians to systematically assess the OHRQoL in edentulous populations thereby enabling them to capture the patients' subjective experiences and prioritize care based on their needs. Incorporating these assessments into routine clinical practice not only allows clinicians to track patient outcomes over time but also encourages shared decision-making by aligning treatment plans with patient priorities.

6.2 Limitations of the Study:

The results of the present study may have limited generalizability and may not be applicable from a global perspective. While our project includes data from edentulous individuals with diverse backgrounds from Montreal, Canada, and San Antonio, US, this is still a narrow demographic and may not be truly representative of explaining the multidimensional concept of OHRQoL. Our results may have greater generalizability within the North American context. However, outside of North America, the healthcare systems, socioeconomic conditions and cultural perceptions of edentulism vary significantly, thereby minimizing the applicability of our findings.

Numerous studies in literature have shown different factor structures based on a specific population, highlighting the variability of how OHRQoL is perceived and experienced by different individuals. It is difficult to identify a specific factor structure that adequately represents the concerns of edentulous individuals. For instance, in regions where access to dental care is limited or in cultures where tooth loss is seen as a natural process associated with ageing, the psychological and social implications of edentulism may be perceived differently than in North America.

The present study is uses baseline data from a Canadian RCT and a US quasi-experimental study These two methodological approaches impact results in distinct ways. First, as discussed above, they affect external validity (the generalizability of findings). Since both RCTs and quasi-experimental studies are analytical epidemiological studies, the sampling of individuals may not be fully representative of the broader population because participants are often selected based on specific criteria rather than random sampling. Second, these approaches may influence the comparability of baseline participant characteristics. In the Canadian RCT, randomization ensures a balanced distribution of baseline characteristics across groups, reducing the influence of external factors on the instrument’s measurements and allowing for a clearer assessment of its validity. In contrast, the quasi-experimental study lacks randomization, potentially resulting in uneven baseline characteristics that could affect instrument outcomes.

The age differences between the US and Canadian cohort is another bias as it may impact the interpretation of our findings. For instance, the EFA is performed on the US population where participants were 25 years and older. This broader age group allows for the exploration of how younger and middle- aged adults perceive their OHRQoL. For instance, younger edentulous individuals may prioritize social interactions over their elder counterparts. When applying EFA on the US population, we found a distinct "Social Impact" reflecting the importance of social well-being among younger edentulous individuals.

6.3 Strengths of the Study:

The present study uses a rigorous methodological approach that combines both the EFA and CFA statistical techniques. EFA is essential in identifying the dimensions of the OHIP-EDENT which influence OHRQoL in edentulous populations. Furthermore, we tested the hypothetical three-factor model derived from EFA on the Canadian population to confirm its robustness. This approach increases the reliability of our findings whilst demonstrating a comprehensive framework to measure OHRQoL.

By testing a four-factor model previously observed in a Brazilian population, our project confirms the cross-cultural applicability of the OHIP-EDENT. Validating both the three-factor (identified from the US cohort) and the four-factor (previously identified from a Brazilian population) in the Canadian population reinforces the reliability of the OHIP-EDENT instrument. Clinicians can assess the different factors which impact OHRQoL in edentulous individuals and focus on tailoring their treatment to address not only functional and aesthetic concerns but to also take psychological and social well-being into account which are often overlooked in traditional clinical care. Additionally, our work also provides both clinicians and researchers to gain an understanding that while common factors persist in evaluating OHRQoL amongst edentulous individuals, specific demographic and cultural factors must also be taken into consideration to provide effective, tailor- made interventions.

Using baseline data from the two studies eliminates potential confounding factors that may be introduced by interventions. This ensures that the factor structure obtained through the analysis accurately represents the concept of OHRQoL in edentulous individuals. This approach ensures a clearer interpretation of the results without the influence of treatment effects.

6.4 Future Directions:

Long-term, longitudinal studies measuring OHRQoL in edentulous populations are necessary to continue building upon the findings presented in this thesis. It is necessary for future investigations to follow edentulous individuals over extended periods of time and evaluate the

trajectory of their overall well-being. This would provide an understanding to clinicians and researchers about the subjectivity of OHRQoL. Additionally, socio-economic factors, access to quality healthcare and cultural perceptions need to be taken into account when measuring oral health outcomes across diverse populations.

Moreover, researchers should also consider adapting and refining the OHIP-EDENT instrument. The OHIP-EDENT, first proposed by Allen and Locker in 2002, has been the most frequently used tool to evaluate OHRQoL in edentulous individuals. Since OHRQoL is subjective and a constantly evolving phenomenon, it is important to make sure that the tool remains culturally sensitive and relevant to diverse edentulous populations across the globe. Several studies in literature have shown different factor structures in comparison to the traditional seven-domain framework. Researchers should consider merging certain domains or creating new ones to better represent OHRQoL.

It is important to conduct research in low- and middle-income countries to better understand the perspectives of these individuals towards edentulism. Such research could provide important information regarding the global experience of OHRQoL. Applying similar methodological approaches across different populations will further enhance the external validity of the findings and contribute to a more comprehensive understanding of the multifaceted nature of OHRQoL.

6.5 Knowledge Translation:

To effectively disseminate the study results and findings to the following academic institutions:

i. Faculty of Dental Medicine and Oral Health Sciences, McGill University, Canada through the positions of my supervisors Dr Nicolau, Dr. Feine and my thesis committee member Dr. Nguyen
ii. Faculty of Dental Medicine, Université through my Thesis committee members Dr. de Souza.
iii. School of Dentistry, University of Maryland, Baltimore, US through the position of my co-author Dr. Oates.

This initiative will encourage discussions amongst clinicians and researchers to consider adaptation and refinement of existing instruments and their implementation in diverse cultural and socioeconomic contexts.

Additionally, I have presented the findings of my research at various academic conferences. I presented a scientific poster at the Journée Scientifique Réseau de recherche en santé

buccodentaire et osseuse 2024. I also had the privilege of delivering an oral presentation on my thesis work at the prestigious Oral Epiforum Symposium organized by the Behavioral, Epidemiologic, and Health Services Research (BEHSR) Group at the IADR Conference 2024 in New Orleans.

Lastly, the manuscript will be submitted to a peer-reviewed scientific journal for publication.

7. CONCLUSION

The overall conclusion of this study is that OHRQoL in edentulous populations requires more nuanced measurement approaches. OHRQoL is an ever-evolving construct, influenced by diverse demographic and cultural factors that shape an individual's perceptions of their oral health and overall well-being. Therefore, it is necessary to develop measurement tools that are not only clinically relevant but also adaptable and sensitive to the unique contexts of different populations. Future research in this domain should consider simplifying the existing models as indicated by our findings. This may enhance the measurement of OHRQoL in edentulous individuals across the globe.

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10. APPENDIX

10.1. METHODOLOGY

This project is a secondary data analysis that draws on baseline data from a randomized controlled trial in Canada and a quasi-experimental study in the United States. [197-198] While extensive sociodemographic and clinical information was collected for all participants (in both studies), the current project will be evaluating only the baseline responses of the OHIP-EDENT questionnaire to assess patients' perceptions of OHRQoL. The details of the two studies are as follows:

10.1.1 Study 1: Canada

10.1.1.1 Overall Study Design:

Randomized controlled trial (RCT) is an experimental study design useful for evaluating the effectiveness of an intervention or a treatment. Researchers randomly assign the participants into either an experimental or a control group (randomization). The experimental group receives the intervention or treatment while the control group may either receive no treatment/ placebo/ another standard of care. RCTs are often considered as the gold standard for establishing causal relationships since randomization ensures that the difference in outcomes is because of the treatment rather than the confounding factors. [199]

For this thesis project, data was drawn from the Canadian site of a RCT that assessed the impact of mandibular conventional dentures (CDs) to implant overdentures (IODs) with two implants on the nutritional status of edentate individuals. The diversity of Canadian population (specifically in Montreal, Quebec) would allow the researchers to develop a comprehensive understanding of the intervention's impact across different demographic groups. Additionally, the well-established research infrastructure at McGill University would have supported high-quality data collection and follow-up assessments. Both groups were required to complete a standardized questionnaire for sociodemographic information, the OHIP-EDENT Instrument as well as The McGill Denture Satisfaction Questionnaire at baseline, 6 months and 12 months post-treatment.

10.1.1.2 Study setting:

Both the experimental and the control groups were recruited from McGill University Health Centre- Royal Victoria Hospital, Montreal, Canada. A total of 255 individuals were recruited in this study, 128 individuals assigned to the experimental group and the remaining 127

participants were assigned to the control group. For the present study, 254 participants were included for the analysis.

10.1.1.3 General Inclusion and Exclusion Criteria:

The eligibility criteria for the study are: (i) patients >=65 years of age, (ii) a minimum edentulous period of 5 years, (iii) individuals who are willing to replace their existing complete dentures, (iv) participants having adequate knowledge of written and spoken English or French, (v) participants who are able to understand the questionnaires used in the study, (vi) those who are willing and able to understand the protocol and provide informed consent

The exclusion criteria for the study are: (i) insufficient bone for placement of 2 implants in the anterior mandible, (ii) participants exhibiting acute or chronic temporomandibular disorder (TMD) symptoms, (iii) relevant medical history that contraindicates implant surgery, (iv) diagnosis of cancer in the last 5 years, (v) Body Mass Index (BMI) < 20 kg/m^2 or >32 kg/m^2, (vi) participants taking dietary supplements, anti-neoplastic medication, phenytoin, or corticosteroids, (vii) Psychological or psychiatric conditions that may impact the treatment

10.1.1.4 Recruitment Procedure:

To recruit participants for the trial, several advertisements were published in French and English local newspapers as well as in a monthly periodical for retired persons. 730 individuals from the Greater Montreal area, who met the initial requirement (through telephone screening) were invited for an in-person information session where the research assistant explained all aspects of the trial and the treatment. Individuals interested in participating in the trial were provided with a clinical examination to assess if they had sufficient bone levels for two implants to be placed in the mandibular anterior region.

A total of 255 edentate elders (Female= 142, Male= 114) participated in this study. The participants were stratified by sex and type 2 diabetes status and then randomly assigned to either the experimental or control groups using a computer-generated permuted block scheme by an offsite data management company.

- Experimental Group: Participants received maxillary CDs and mandibular IODs in two implants with ball attachments ((ITI, Straumann-048.242/243, Waldenburg, Switzerland) placed into the canine region of the anterior mandible.
- Control Group: Participants received maxillary and mandibular CDs.

10.1.1.5 Ethics Approval and Informed Consent:

The study protocol was approved by the McGill University Institutional Review Board and the Ethics Committees at l'Université de Montréal (International Clinical Trial Registration #ISRCTN24273915). The clinical assessments took place at the McGill University Health Centre (MUHC) - Royal Victoria Hospital. The participants were explained in detail about information collection for research purposes and the objectives of the study. Signed consent forms were obtained from all individuals, and they also received financial compensation for their participation. The data obtained was anonymized and participants were provided with unique identification numbers to protect their personal information and identity.

10.1.1.6. Study Measurements:

10.1.1.6.1 Questionnaires:

The RCT used the following questionnaires to collect information on all participants at baseline, 6 months and 12 months post rehabilitative treatment:

a. **OHIP-EDENT Instrument:**

The OHIP-EDENT questionnaire was developed by Allen and Locker from the original OHIP-49. This instrument specifically measures OHRQoL in edentulous patients. [8] The OHIP-EDENT instrument comprises of 20 questions pertaining to masticatory capacity, pleasure in eating, level of comfort and assuredness while wearing the prosthesis, and relationship problems, among others. [192] The items are rated on six-point Likert scales (''never'' = 1, ''rarely'' = 2, ''occasionally'' = 3, ''often'' = 4, ''very often'' = 5 or ''all of the time'' = 6). The total range of OHIP-EDENT is between 20–120 points, with lower scores indicating better oral health-related quality of life. Participants recruited in the trial completed this questionnaire at baseline, 6 months and 12 months post treatment so as to measure OHRQoL before and after receiving the prostheses.

b. **McGill Denture Satisfaction Questionnaire:**

The McGill Denture Satisfaction Questionnaire was first developed in the 1990s and used worldwide in clinical studies. [200-201] This tool is a treatment-specific patient reported outcome measure (PROM) used to evaluate satisfaction with the mandibular denture. The responses are collected using the 100mm visual analogue scale (VAS scale) with the end points being labelled as "extremely satisfied" or "not at all satisfied". An example of such a question would be ''In general, are you satisfied with your oral condition?'' The tool effectively captures the patient's perception of general satisfaction, ease of use, stability and support of the prostheses. Individuals can also rate their masticatory efficiency, ease

of cleaning, speech ability and their overall oral health status before and after receiving rehabilitative treatment.

c. **Questionnaire for Sociodemographic Information:**

A standardized questionnaire was used to collect data on age, gender, native language, education level, annual household income, marital status and accommodation (living alone/ with family/ or shared accommodation). Additionally, the BMI was calculated from each person's height and weight.

10.1.1.6.2. Biological Sample Collection:

The primary outcome of the RCT was to evaluate the blood serum concentration of important markers of general health such as homocysteine[tHcy], folate, vitamin B6, vitamin B12, C-reactive protein (CRP), and albumin. All nutritional assessments were conducted at three time points: baseline, 6 months, and 12 months after receiving the prostheses. Participants were requested to provide venous samples in a fasting state. The blood samples were drawn from the antecubital vein and sent for laboratory analysis. Plasma vitamin B12 and serum levels of albumin, hypersensitivity C-Reactive Protein (with a detection limit of 0.02 mg), and folate levels were examined. Blood samples that were not immediately tested were centrifuged at -4°C for 10 minutes. The resultant supernatant was stored at -80°C for future examination. A radioenzymatic test was used to determine the concentration of vitamin B6, in the form of pyridoxal 5-phosphate, within one month of collection. Total homocysteine (tHcy) levels were evaluated using Bayer HealthCare's ADVIA Centaur® System, a competitive immunoassay. When [tHcy] exceeded 25 μmol/L, samples were re-measured using High Performance Liquid Chromatography (HPLC) with fluorometric detection.

10.1.2 Study 2: United States

10.1.2.1 Overall Study Design:

Quasi-experimental studies are similar to randomized clinical trials with the exception that the patients are assigned to different treatment groups either through their own choice or by their healthcare providers, instead of being randomized. This lack of randomization presents challenges in achieving strong internal validity. Without random assignment, it becomes difficult to control for confounding variables, which can obscure the true causal relationships between the intervention and outcomes. As a result, researchers may risk misinterpreting the findings of the study due to unaccounted biases and confounders. [202]

For this thesis project, the data was obtained from a quasi-experimental study conducted from 2007 to 2012, at the University of Texas Health Science Centre at San Antonio, USA. [198]. The study design is based on real-world clinical scenario where patients and healthcare providers work together so that the best standard of care is delivered. The main objective of the study was to assess the effect of glycemic levels on implant-related outcomes amongst edentulous patients receiving mandibular implant-supported overdentures. Randomization may perhaps not be possible in this scenario, thereby making the quasi-experimental approach more feasible. The participants were required to complete the OHIP-EDENT Questionnaire, The McGill Denture Satisfaction Questionnaire and provide HbA_{1c} levels at baseline, 6 months and 12 months post treatment.

10.1.2.2 Study setting:

A total of 165 individuals were recruited at the School of Dentistry, University of Texas Health Science Center at San Antonio (UTHSCSA) to participate in this study. For the present thesis work, baseline OHIP-EDENT data of 155 participants is included for analysis.

10.1.2.3 General Inclusion and Exclusion Criteria:

The eligibility criteria for the study are: (i) edentulous patients >=25 years of age requiring a mandibular implant overdenture (two implants in the mandibular anterior region), (ii) patients who were diagnosed with T2DM, (iii) participants with a baseline HbA_{1c} level < 5.9 percent or a fasting blood glucose level <100 mg/dL, (iv) participants with clinically acceptable complete dentures for at least six months, (v) dental implant therapy was limited to the mandibular anterior region in the canine-premolar area with sufficient bone volume (for placing of 4.1-mm diameter implants with a length of 8 to 12 mm, (vi) extraction sites requiring at least four months of healing prior to implant placement.

The exclusion criteria for the study include: (i) HbA_{1c} level >12 percent at the time of screening, (ii) medical conditions other than type 2 diabetes mellitus which are considered as contraindications to implant surgery, (iii) patients undergoing antiresorptive drug therapy, pregnant women, patients who reported smoking, untreated oral infections, viral or autoimmune disease, (iv) implant sites that previously underwent bone-grafting procedures with autogenic or allogeneic materials in the last one year, (v) implant sites that had previously undergone grafting with alloplastic materials

10.1.2.4 Recruitment Procedure:

A total of 165 edentate individuals were recruited at the School of Dentistry, University of Texas Health Science Center at San Antonio (UTHSCSA) from September 2007 through June 2012 to participate in this study. 8 participants had to drop out of the study as they were not eligible to receive implants. The remaining 157 participants were divided into three groups depending on whether they had received a diagnosis of T2Dm or not. All three groups received two transmucosal implants (4.1-mm diameter and 8-, 10- or 12-mm length, SLActive, Straumann, Basel, Switzerland) in the anterior mandible to support a mandibular overdenture.

The patients were classified according to their HbA_{1c} levels as follows:

- Group 1 (N=57): Participants with HbA_{1c} levels <=5.9 percent
- Group 2 (N=65): Participants with HbA_{1c} levels between 6.0-8.0 percent
- Group 3 (N=29): Participants with HbA_{1c} levels>= 8.1 percent

10.1.2.5 Ethics Approval and Informed Consent:

The ethical approval for this quasi-experimental study was granted by the Institutional Review Board at the University of Texas Health Science Centre at San Antonio, Texas, US. The participants were explained in detail about information collection for research purposes and the objectives of the study. Signed consent forms were obtained from all participants. The data obtained was anonymized and participants were provided with unique identification numbers to protect their personal information and identity.

10.1.2.6. Study Measurements:

10.1.2.6.1 Questionnaires:

The quasi-experimental study used the following questionnaires to collect information on all participants at baseline, 6 months and 12 months post rehabilitative treatment:

a. OHIP-EDENT Instrument:

The OHIP-EDENT Instrument was used to measure the OHRQoL in edentulous patients. [8] The OHIP-EDENT instrument is specific to edentulous patients and includes questions pertaining to masticatory capacity, pleasure in eating, level of comfort and assuredness while wearing the prosthesis, and relationship problems, among others. The total score is obtained by summing the individual scores of each item of the questionnaire. A lower score indicates better oral health-related quality of life.

b. The McGill Denture Satisfaction:

Patient satisfaction with the prostheses was assessed by The McGill Denture Satisfaction Instrument. [192] This is a PROM used to assess patient satisfaction with the mandibular denture. The responses are collected using the 100mm visual analogue scale (VAS scale) with the end points being labelled as “extremely satisfied” or “not at all satisfied”. The tool effectively captures the patient’s perception of general satisfaction, ease of use, stability and support of the prostheses. Individuals can also rate their masticatory efficiency, ease of cleaning, speech ability and their overall oral health status before and after receiving rehabilitative treatment.

10.1.2.6.2. Biological Sample Collection:

Venous blood samples were obtained during the enrollment sessions to evaluate the HbA_{1c} levels and determine the participant’s eligibility for the trial. Samples were also taken at baseline (surgery), two months and four months post-surgery (implant loading), and three, six, and twelve months after inserting the Locator attachments. A single commercial laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) examined all blood specimens. The study considered baseline values (≤ two weeks before surgery) as well as HbA1c levels measured six and twelve months after restoration.

10.1.3. STATISTICAL ANALYSIS

10.1.3.1 Selection of Study Variables:

For this thesis project, we have used the OHIP-EDENT tool which is used to assess OHRQoL in edentulous individuals. The instrument comprises 20 questions across 7 dimensions: functional limitation (3 questions), physical pain (4 questions), psychological discomfort (2 questions), physical disability (4 questions), psychological disability (2 questions), social disability (3 questions) and handicap (2 questions). Each item is rated on a six-point Likert scale ranging from (1=Always, 2= Most of the time, 3=Some of the time, 4=Occasionally,5=Rarely, 6=Never). The total OHRQoL score is calculated by summing the scores from all 20 items, providing an overall measure of the individual's perceived OHRQoL. The OHIP-EDENT scale used, where "Always" is scored as 1 and "Never" as 6, a higher score is associated with better OHRQoL. A lower score means that the individual frequently experiences problems related to their oral health, such as discomfort, pain, or limitations in function, while a higher score suggests that the individual rarely or never encounters these issues, reflecting a better OHRQoL.

10.1.3.2 Data Analysis:

10.1.3.2.1 Introduction to Factor Analysis:

For the present study, we have used factor analysis, a type of statistical technique that evaluates the construct validity of an instrument. Factor analysis falls under the umbrella of multivariate analysis which was initially developed by psychologists to analyze the matrices of correlations between cognitive tests variates. The pioneers of this statistical technique were Spearman, Thomson, Thurstone, and Burt. [203] Research in fields such as psychology and the social sciences is often comprised of variables that cannot be directly measured. These are referred to as *latent variables* and include constructs such as quality of life, personality, intelligence, etc. By using factor analysis, researchers can group individual items of an instrument (variables that can be measured) with common characteristics under a specific theoretical construct (latent variable). Most often, the objective behind performing factor analysis is to reduce the items in a questionnaire by identifying the underlying structure of a dataset so that it may be possible to explain the data with fewer domains. Additionally, factor analysis is also useful for hypothesis testing about the data's factor structure. [204] There are two main conceptual approaches to factor analysis, and our study has used both exploratory and confirmatory factor analysis tests for the available data (with respect to the OHIP-EDENT instrument).

10.1.3.2.2 Exploratory Factor Analysis (EFA):

Exploratory Factor Analysis or Common Factor Analysis is a popular dimension reduction statistical technique that helps to identify the underlying structure of an instrument. The purpose of performing an EFA is to cluster variables that are highly correlated (to each other) and create a domain (also known as a factor) that is representative of certain characteristics common amongst the selected variables. [205] EFA, first employed by Spearman in 1904, is grounded in philosophical and statistical principles. Since then, EFA has been used widely in the assessment of theories and validation of measurement instruments. [206-207] Some of the practices that need to be followed while performing an EFA are as follows:

a. ***Data Inspection Techniques:*** It is important to evaluate whether the dataset meets certain requirements prior to performing an EFA. The two most widely used inspection techniques include the Kaiser-Meyer Olkien (KMO) Test as well as the Bartlett Test of Sphericity. [208-209] Both methods assess whether a particular dataset contains sufficient relationships to justify performing an EFA. The Bartlett's Test determines whether the observed correlation matrix resembles an identity matrix in which all the off-diagonal elements are zero. [210] A significant result from Bartlett's Test suggests that the data do

not conform to an identity matrix which would make it appropriate for an EFA. In contrast, the KMO Test measures the proportion of common variance within a dataset. [209] With respect to, the KMO Test, values > 0.60 are considered suitable for performing EFA, with values between 0.9-1 being considered excellent. Both the KMO and Bartlett tests should be significant to ensure that the assumptions of EFA are not being violated. [211] Additionally, a sufficient sample size is necessary to perform EFA. Amongst the several recommendations, a sample size of 200 to 500 individuals with a participant-to-variable ratio from 5:1 to 20:1 is recommended. [212-213]

b. ***Factor Extraction Methods:*** There are several strategies or estimation methods used to extract factors while performing EFA. The most popular extraction techniques include principal component analysis (PCA), least squares, maximum likelihood, principal axis factoring, alpha factoring, and image factoring. Each of these techniques relies on the nature of data, normality assumptions, and model error that affect how well each of these would perform in specific conditions. [213] The Maximum Likelihood (ML) Method is known for its generalizability, whilst highlighting the larger correlations. [214] However, the ML technique is sensitive to skewed data and outliers. [215] Methods such as Minimum Residuals (MINRES) and Unweighted Least Squares (ULS) are less constrained by distributional assumptions and are often considered equivalent. While MINRES minimizes the least squares directly, ULS focuses on reducing the eigenvalues of the correlation matrix. [216] For the present study, we have used the ULS Estimation Technique. This is because, the assumption of normality is often violated with ordinal data and the ULS technique is well-equipped to handle ordinal data, such as the Likert-type responses observed with instruments like OHIP-EDENT. [217]

c. ***Factor Retention Methods:*** The aim of EFA is to identify a specific number of factors within the observed correlation matrix. The ideal number of factors should be such that adding an additional factor provides no benefit, whilst removing a factor significantly worsens the model's performance. Several strategies are available for determining the number of factors to be retained such as the Kaiser criterion, visual scree plot analysis and parallel analysis. Most of these techniques rely on eigenvalues, which represent the variance amongst the observed variables explained by each common factor. Eigenvalues are derived by adding the squared factor loadings; factors with small eigenvalues indicate minimal shared variance and, thus, should be excluded from the analysis. [218]

i. Kaiser criteria: By implementing this criterion, all factors with eigenvalues greater than one must be retained. However, several studies have reported that the Kaiser criterion is considered the least accurate method since factors with almost identical eigenvalues of 0.99 and 1.01 usually receive different retention decisions. Hence, researchers are encouraged to apply other retention techniques to identify the appropriate number of factors. [173]

ii. Scree plot: Another popular factor retention technique is the visual scree plot analysis where researchers plot individual eigenvalues on a graph until the decrease between consecutive eigenvalues becomes minimal, forming a distinct "elbow". Factors with eigenvalues that appear before this elbow are retained, as they are believed to account for a significantly greater portion of common variance than those that follow the elbow. [219]

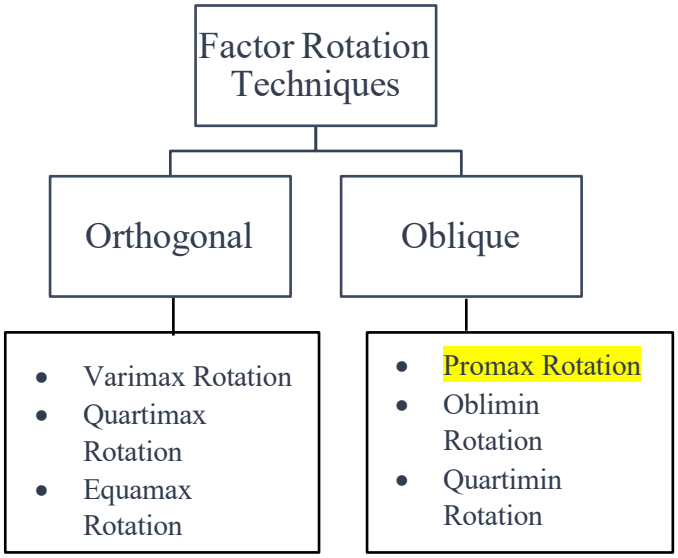
iii. Parallel analysis: This technique creates multiple randomized datasets with the same number of variables and cases as the original dataset. These randomized datasets are subjected to EFA, and the average or 95^{th} percentile of each eigenvalue is considered. The process is repeated several times, and the eigenvalues from the randomized datasets are compared to those of the original dataset. The factors are retained if the eigenvalues exceed the corresponding values from the randomized datasets. [220]

For the present study, we have used all the above retention techniques to identify the relevant number of factors that should be included in our model.

d. Factor Rotation Techniques: Once the number of factors has been identified, the individual loadings need to be interpreted. However, unrotated results from EFA are often difficult to interpret. Factor loadings indicate how strongly one item or variable is related to the underlying factor. Rotating the axes helps to make the relationship between factors and variables apparent. By applying rotation techniques, both strong and weak associations can be identified, thereby making it easier to see which items can be grouped under a specific factor or domain. There are two types of rotation techniques depending on the angle formed between the X and Y axes. This includes the orthogonal and oblique rotation methods. The orthogonal rotation technique is used when the underlying factors are not correlated (i.e., an angle of 90^{o} is maintained between both the X and Y axes). In contrast, the oblique rotation technique is applied when the assumption is that the underlying factors are correlated to each other (i.e., the X and Y axes create an angle other than 90^{o}). [221]

Concerning the OHIP-EDENT Instrument, the original instrument consists of 20 items under 7 factors or domains. These items are believed to be highly correlated with each other and therefore, we have used the Promax technique (oblique rotation) to better interpret the factor loadings.

Figure 6: Different Factor Rotation Techniques



10.1.3.2.3 Confirmatory Factor Analysis (CFA):

The Confirmatory Factor Analysis technique is a hypothesis testing model as opposed to the Exploratory Factor Analysis which is a hypothesis generating technique. CFA is performed once a solid theoretical foundation has been established by identifying the factor structure that is backed by strong evidence through several EFA studies. In such situations, CFA proves to be an important statistical technique to a) evaluate how well the proposed latent factor model fits the observed data, and b) compare multiple models and assess the best fit for the given data. [222] CFA can be used to evaluate measurement invariance, validate constructs, and measure the psychometric properties of an instrument. [222] Researchers need to take the following elements into account while performing CFA:

a. ***Matrix Formation:*** All CFAs start with either a correlation or covariance matrix to examine the relationships amongst all the variables in a dataset. CFA uses the matrix to test a predefined model and evaluate how the underlying latent factors affect the observed variables. The matrix helps estimate factor loadings and check how well the model matches the data. [224]

b. ***Specification:*** Unlike EFA, which is used to identify the most relevant factors or associations that align with a given set of variables, CFA is only applicable when a predefined model is established beforehand. The most challenging aspect of this statistical technique is to determine the identity of unknown parameters. [225] In a CFA model, a parameter is identified when it has a single value, either by being fixed or calculated based on fixed parameters. [226]

c. ***Estimation:*** The values of the free parameters are estimated once the CFA model has been specified. There are several estimation methods that can be applied while performing CFA. The choice of estimation depends on the nature of the dataset. Maximum likelihood (ML) estimation is the technique most commonly used. However, the ML assumes that the data is continuous and follows multivariate normality; therefore, it is not recommended for ordinal data. [227] Other estimation techniques include diagonally weighted least squares, unweighted least squares, and the generalized least squares techniques. [228]

d. ***Model Fit Indices:*** There are numerous fit indices available to evaluate the goodness of fit of the CFA model. Some of the popular fit indices are as follows:

Table 3: Fit indices used to evaluate CFA models

Measure	Name	Description	Cut-off for good fit
X2	Model Chi-Square	Assess the overall fit and the discrepancy between the sample and fitted covariance matrices. Sensitive to sample size.	p-value> 0.05
GFI	Goodness of Fit	GFI is the proportion of variance accounted for by the estimated population covariance.	GFI ≥ 0.95
NFI TLI	Normed-Fit Index Tucker Lewis index	An NFI of 0.95 indicates the model of interest improves the fit by 95% relative to the null model. TLI is recommended for smaller samples.	NFI ≥ 0.95 TLI ≥ 0.95
CFI	Comparative Fit Index	Compares the fit of a target model to the fit of an independent, or null, model.	CFI ≥ 0.90
RMSEA	Root Mean Square Error of Approximation	Values closer to 0 represent a good fit.	RMSEA < 0.08

SRMR	Standardized Root Mean Square Residual	The square-root of the difference between the residuals of the sample covariance matrix and the hypothesized model.	SRMR <0.08

10.1.3.2.4 Data Analysis - Step-by-Step Process:

We will be using baseline data from both the Canadian and US studies to ensure the robustness, reliability, and generalizability of our findings. Using baseline data is a recommended practice for factor analysis as it represents an individual's natural response, free from the effect of an intervention. This helps us to understand the relevant factors that contribute to the concept of OHRQoL. [229]

All statistical analyses were performed using the R Project for Statistical Computing Version 4.3.2 and performed in three steps to address each of the objectives of the study:

a. Objective 1: To identify the underlying factor structure of the OHIP-EDENT questionnaire using the EFA technique on data from a US population:

- After excluding 11 participants, a total of 154 participants were included in the initial EFA analysis. The Kaiser-Meyer Olkin and Bartlett's Tests were performed to determine if the EFA technique can be applied to the US population. To assess dimensionality, the ratio of first-to-second eigenvalue, Cattell's scree plot, and Horn's parallel analysis. A first-to-second eigenvalue ratio greater than four indicates unidimensionality. Horn's parallel analysis compares observed eigenvalues against random eigenvalues, retaining the number of observed eigenvalues that are greater than the simulated eigenvalues. This data-driven approach reinforces the relevant number of factors that needed to be extracted to explain the OHRQoL construct measured by the OHIP-EDENT. Since the items of the OHIP-EDENT questionnaire are highly correlated, the Principal Axis Factoring (PAF) Technique, along with the Promax oblique rotation technique were used.

b. Objective 2: To apply a hypothesis-testing confirmatory factor analysis technique on data from a Canadian population to determine the relevant number of factors that adequately represent the OHRQoL construct measured by OHIP-EDENT.

- In CFA, the researcher tests the factor structure identified in EFA on an independent dataset to confirm its validity. In this case, we have extracted the appropriate domains of the OHIP-EDENT that adequately represent OHRQoL from the responses of the US population. The

model determined through the EFA technique was validated through the CFA approach on the Canadian population. We have used the ULS Estimation Method to perform CFA.

c. Objective 3: To evaluate the cross-cultural applicability of the OHIP-EDENT by testing an alternative factor structure proposed in the literature on the Canadian population.

- A four-factor solution previously observed in a Brazilian edentulous population (through an EFA) was applied to the Canadian population of the present study. CFA was conducted with these four parameters to evaluate the most important constructs that explain OHRQoL across diverse populations and cultural settings.

10.1.3.2.5 Missing Values:

Participants who had missing responses for more than 5 items of the questionnaire were excluded from the analysis to not compromise the accurate interpretation of the OHIP-EDENT structure. To address missing data for OHIP-EDENT responses (less than 5 responses missing), we used a median imputation strategy. For the present analysis, a total of 254 participants (out of 255) in the Canadian cohort and 154 (out of 156) from the US population have been included. This technique is beneficial to maximize the dataset's utility whilst ensuring that sufficient data are available for each individual to adequately assess their OHRQoL at baseline. By using the mean imputation strategy, we were able to create a balance by minimizing bias from complete case exclusion and avoiding dependence on incomplete datasets. This not only allows us to preserve the factor structure but also increases the generalizability of our findings. [230]

10.2 OHIP-EDENT QUESTIONNAIRE:

OHIP-20E Questionaire

Identification code : ☐☐☐☐☐☐☐☐☐☐

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

This questionnaire was designed to evaluate how your oral condition has affected your quality of life **during the past month**. For each of the following questions, mark the response that you feel is the best. If a question does not apply to your situation, then please indicate this just below the question.

	In the last month:	Always	Most of the time	Some of the time	Occasionally	Rarely	Never
1	Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
2	Have you had food catching in your teeth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
3	Have you felt that your dentures have not been fitting properly?	O 1	O 2	O 3	O 4	O 5	O 6
4	Have you had painful aching in your mouth?	O 1	O 2	O 3	O 4	O 5	O 6
5	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
6	Have you had sore spots in your mouth?	O 1	O 2	O 3	O 4	O 5	O 6
7	Have you had uncomfortable dentures?	O 1	O 2	O 3	O 4	O 5	O 6
8	Have you been worried by dental problems?	O 1	O 2	O 3	O 4	O 5	O 6
9	Have you been self conscious because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
10	Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
11	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6
12	Have you been unable to eat with your dentures because of problems with them?	O 1	O 2	O 3	O 4	O 5	O 6
13	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	O 1	O 2	O 3	O 4	O 5	O 6

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	In the last month:	Always	Most of the time	Some of the time	Occasionally	Rarely	Never
14	Have you been upset because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
15	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
16	Have you avoided going out because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
17	Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
18	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
19	Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
20	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6

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