Université de Montréal

The impact of nocturnal wear of the prosthesis on the oral health-related quality of life of an apneic edentulous population

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Ce mémoire intitulé:

The impact of nocturnal wear of the prosthesis on the oral health-related quality of life of an apneic edentulous population

Présenté par :
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A été évalué par un jury composé des personnes suivantes

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Résumé

Problématique : La perte de dents est l'une des maladies chroniques associées à plusieurs altérations anatomiques et fonctionnelles de la cavité buccale et des voies respiratoires supérieures. Ces changements entraînent une détérioration de la qualité de vie liée à la santé bucco-dentaire (OHRQoL), en particulier chez les personnes âgées. Les prothèses complètes permettent d'améliorer l'apparence et peuvent restaurer certaines fonctions masticatoires altérées par l'édentement, créant ainsi un impact positif sur la qualité de vie liée à la santé buccodentaire. Cependant, le port continu des prothèses dentaires pendant la nuit, peut amener des problèmes de santé buccodentaires. Toutefois, certaines études ont montré que le fait de dormir avec une prothèse dentaire avait un impact positif sur la qualité du sommeil et la qualité de la vie.

Objectifs : L'objet de ce projet de maîtrise est d'étudier l'impact du port nocturne des prothèses complètes sur l'OHRQoL, chez les patients âgés édentés et souffrant d'apnée obstructive du sommeil (AOS).

Méthodologie : Ce projet de maîtrise est imbriqué dans un essai clinique croisé randomisé portant sur 70 patients âgés (65 ans et plus), complètement édentés et diagnostiqués avec une AOS modérée à sévère (IAH ≥ 10). Les participants ont été assignés au hasard à l'un des deux groupes (dormant avec ou sans les prothèses dentaires dans un ordre inverse), pendant deux périodes de 30 jours. Les données sur les effets du port nocturne des prothèses dentaires sur la qualité de vie liée à la santé et la qualité de vie liée à la santé buccodentaire ont été recueillies au début et au cours des deux visites de suivi, à l'aide du questionnaire *Oral Health Impact Profil* **(**OHIP-20) et du formulaire abrégé SF-36 respectivement. L'analyse des données a été réalisée à l'aide de modèles à effets mixtes pour les mesures répétées, considérant notamment le type d'intervention (dormir avec ou sans prothèses), la séquence d'intervention et la période.

Résultats: Les résultats rapportés ci-dessous sont basés sur les données recueillies auprès de 63 patients. Le score global de l'OHIP-20 était légèrement plus élevé, mais non significatif (p=0.08), chez les patients qui dormaient avec leurs prothèses que chez ceux qui dormaient sans prothèses. Les scores de toutes les sous-échelles du questionnaire OHIP-20 ont augmenté chez

les patients qui dormaient avec leurs prothèses, à l'exception de l'incapacité sociale, qui a légèrement diminué, et de handicap qui est resté inchangé. Cependant, l'impact négatif significatif n'a été signalé que pour deux scores de l'OHIP-20 : psycho-inconfort (p = 0,04) et incapacité physique (p = 0,05). Les scores OHIP-20 n'ont été influencés ni par la séquence de randomisation ni par le nombre de visites, à l'exception des scores de handicap, qui ont légèrement augmenté chez les sujets assignés à dormir avec leurs prothèses dentaires au cours de la première période de cette étude.

En revanche, les résultats du SF-36 ont montré une amélioration des scores moyens de toutes les sous-échelles chez les personnes dormant avec leurs prothèses, mais les seuls impacts significatifs étaient constatés sur les aspects de la fonction sociale et du changement de l'état de santé (p <0,01 et p = 0,01 respectivement). La séquence d'attribution a eu un effet significatif sur la fonction physique (p = 0,03), la douleur (p = 0,02) et le changement de santé (p = 0,02). Le nombre de visites de suivi n'a eu un impact significatif que sur le domaine de la fonction physique (p = 0,03).

Conclusion : Bien que dormir avec les prothèses dentaires puisse avoir un impact négatif sur les aspects psychiques et physiques d'OHRQoL, il pourrait également avoir un impact positif sur les aspects sociaux de la fonction et des changements de santé de la HRQoL. Les résultats de la recherche de ce travail de maitrise doivent être considérés comme préliminaires car l'analyse totale des données n'est pas encore terminée.

Mots-clés : Qualité de vie liée à la santé bucco-dentaire, qualité de vie liée à la santé, personnes âgées, prothèses complètes, apnée du sommeil

ABSTRACT

Problematic: Tooth loss is one of the chronic diseases associated with several anatomical and functional alterations in the oral cavity and the upper airway tract. These changes result in the deterioration in oral health-related quality of life (OHRQoL), particularly among the elderly. Complete dentures can enhance the appearance and restore some impaired masticatory functions, creating a positive impact on OHRQoL. However, continuous nocturnal wear of dentures may raise oral health problems. In contrast, some studies have found that the impact of sleeping with dentures is positive with regard to the quality of sleep and quality of life.

Objectives: The aim of this Master's study is to investigate the impact of sleeping with dentures on OHRQoL in edentulous elderly patients who suffer from obstructive sleep apnea (OSA).

Methodology: This master research project is nested in a randomized, crossover trial study of 70 edentulous elderly patients diagnosed with moderate to severe OSA (AHI ≥10). The participants were randomly assigned to one of two groups (sleeping with or without the prosthesis in opposite order), for two periods with a 30-day interval between them. Data on the effect of nocturnal wearing of dentures on OHRQoL and health-related quality of life (HRQoL) were collected at the baseline and during the two follow-up visits, using the Oral Health Impact Profile (OHIP-20) and Short form (SF-36) questionnaires respectively. Data analysis was performed using mixed effect models appropriate for repeated measures including types of intervention (sleeping with or without dentures), sequence and visit number.

Results: Results reported below are based on data collected from 63 patients. The overall OHIP-20 score was slightly higher among patients who wore their dentures while sleeping than in those who did not, but not at a significant level (p=0.08). The scores of all OHIP-20 subscales were increased among patients who slept with prosthesis, except for the social disability which slightly decreased, and the handicap remained at the same average. However, the significant negative impact was reported only for two OHIP scores: psycho-discomfort (p=0.04) and physical disability (p=0.05). OHIP-20 scores were influenced neither by the assignment sequence nor by the period, with an exception for handicap scores which slightly increased among elders assigned to sleep with dentures in the first period of this study.

In contrast, SF-36 results showed an improvement in the mean scores in all subscales among the elderly when participants were sleeping with dentures, but the only significant impacts were found on social function and health change aspects (p <0.01, and p=0.01, respectively). The assignment sequence had a significant effect on physical function (p=0.03), pain (p=0.02), and health change (p=0.02). The follow-up visit number had a significant impact only on the physical function domain (p=0.03).

Conclusion: While sleeping with dentures could have a negative impact on psycho-discomfort and physical discomfort aspects of OHRQoL, it could have a positive impact on the social function and health change aspects of HRQoL. The results of this Master's research should be considered as preliminary since the total data analysis has not completed yet.

Keywords: Oral health-related quality of life, health–related quality of life, elders, complete dentures, sleep apnea

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LIST OF SYMBOLS AND ABBREVIATIONS

AHI	Apnea/Hypopnea Index
ANOVA	One-Way Analysis of Variance
BMI	Body Mass Index
CBCT	Cone-Beam Computed Tomography
HRQoL	General Health-Related Quality of Life
MCS	Mental Component Summary
OHRQoL	Oral Health-Related Quality of Life
OHIP	Oral Health Impact Profile
OHIP-14	Original English Version of Short-Form Oral Health Impact Profile
OHIP-20	20- Item Oral Health Impact Profile Appropriate for use in edentulous patients
OHIP-49	49- Item Oral Health Impact Profile
OHIP-EDENT	Shortened Version of the Oral Health Impact Profile Appropriate for use in edentulous patients
OSA	Obstructive sleep apnea
PCS	Physical Component summary
PSG	Polysomnography
QOL	Quality of life
RCT	Randomized controlled trial
SD	Standard deviation
SF-36	36-item Short-Form
SPSS	Statistical Package for the Social Sciences
VDO	Vertical dimension of occlusion
WHO	World Health Organization

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Finally, my deep love and gratitude to my family, my husband Basel, and my lovely children Joude and Melody, for standing by me and giving me the strength to overcome the challenges along my way.

DEDICATION

This work is dedicated to my late mother, who set the best example of how to overcome many life challenges.

I would like to dedicate my thesis to my children, Joude and Melody, to let them know that education and development is a lifelong process and goals can be reached at any age or stage in life.

A final dedication, to all the elderly who are looking for better quality of life.

CHAPTER 1: LITERATURE REVIEW

1.1 INTRODUCTION

While life expectancy has increased rapidly in the last decades worldwide, the rates of geriatric problems have also increased, showing a great impact on health and oral health-related quality of life for elders and, indirectly, on society. Edentulism is a chronic disease among the elderly around the world. It is not a life-threatening disorder, but remains one of the burdensome diseases that affect the health of the elderly and impair their oral health-related quality of life (OHRQoL) (1-3).

Edentulism is one of the chronic diseases associated with psychological and physiological alterations that may contribute to deterioration in several aspects of the elderly lifestyle, including masticatory functioning, social role performance, sleep quality, and OHRQoL (4-8). The wearing of complete dentures improve OHRQoL among edentulous patients (9). However, wearing dentures can raise numerous issues such as a masticatory dysfunction, pain and discomfort, which may have a negative impact on OHRQoL (10, 11). A higher prevalence of denture-related diseases such as denture stomatitis and respiratory infection (12, 13) has been found among patients who sleep with their dentures. However, the association between nocturnal wear of dentures, OHRQoL and sleep quality has not yet been fully comprehended (14, 15).

In this randomized controlled crossover trial we investigate the impact of sleeping with dentures on OHRQoL among the edentulous elderly participants with obstructive sleep apnea (OSA). Then we present our findings and results.

1.2 ORAL HEALTH-RELATED QUALITY OF LIFE

1.2.1 Definition

Over the past few decades, the concept of oral health-related quality of life (OHRQoL) has attracted the attention of many dentistry researchers and clinicians since several research studies showed that oral health has an impact on general health and well-being (7, 16-25).

This interest is also relevant to the concept of health promotion, particularly in relation to "healthy years of life" in the elderly population (26).

Historically, the concept of OHRQoL emerged in the literature in the early 1980s, following health-related quality of life (HRQoL) concepts that first appeared in the 1960s (27).

The definition of HRQoL is nested in the definition of health introduced by the World Health Organization in 1948: *"state of complete physical, mental, and social well-being and not merely the absence of disease and infirmity"*(28).

Accordingly, in the medical literature, the term HRQoL refers to physical, mental, emotional, and social aspects of health which are influenced by the individual's experiences, perception, and expectation of life (29). Consequently, the term OHRQoL defines the dimension of HRQoL that is related to oral health (30).

In the last century, several definitions and conceptual frameworks have been introduced to better explain the concept of HRQoL and OHRQoL (31). Ware's conceptual models appeared in the literature in 1984 (6, 32) to illustrate the five principal components of HRQoL: disease, personal functioning, psychological distress/well-being, general health perceptions, and social functioning (Figure 1.1).

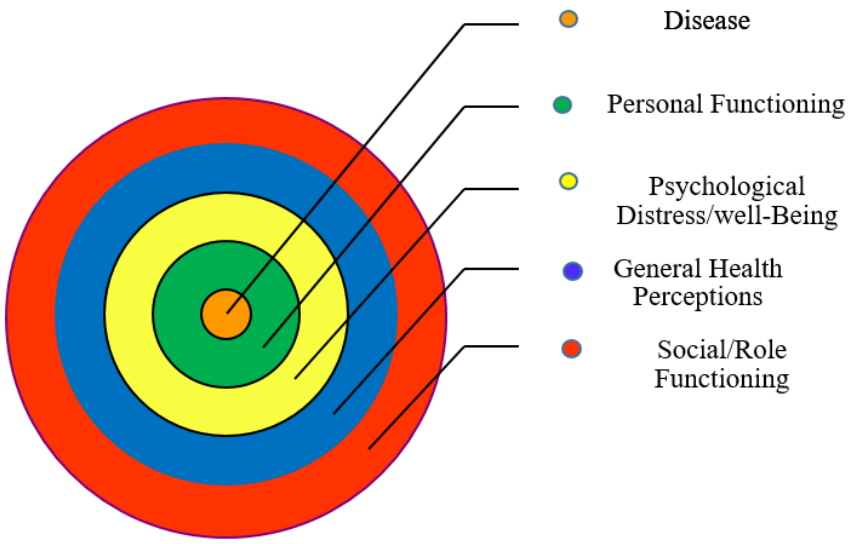


Figure 1.1 Ware's conceptual model of HRQoL (32)

In 1988, Patrick and Erickson (6, 33) defined HRQoL as "*The value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy.*" This definition added to the five broad components of HRQoL new elements such as impairment, injury, treatment, and policy (33).

In 1990, Patrick and Bergner (7) presented a conceptual framework to explain the expected relationship among the five components of HRQoL (Figure 1. 2).

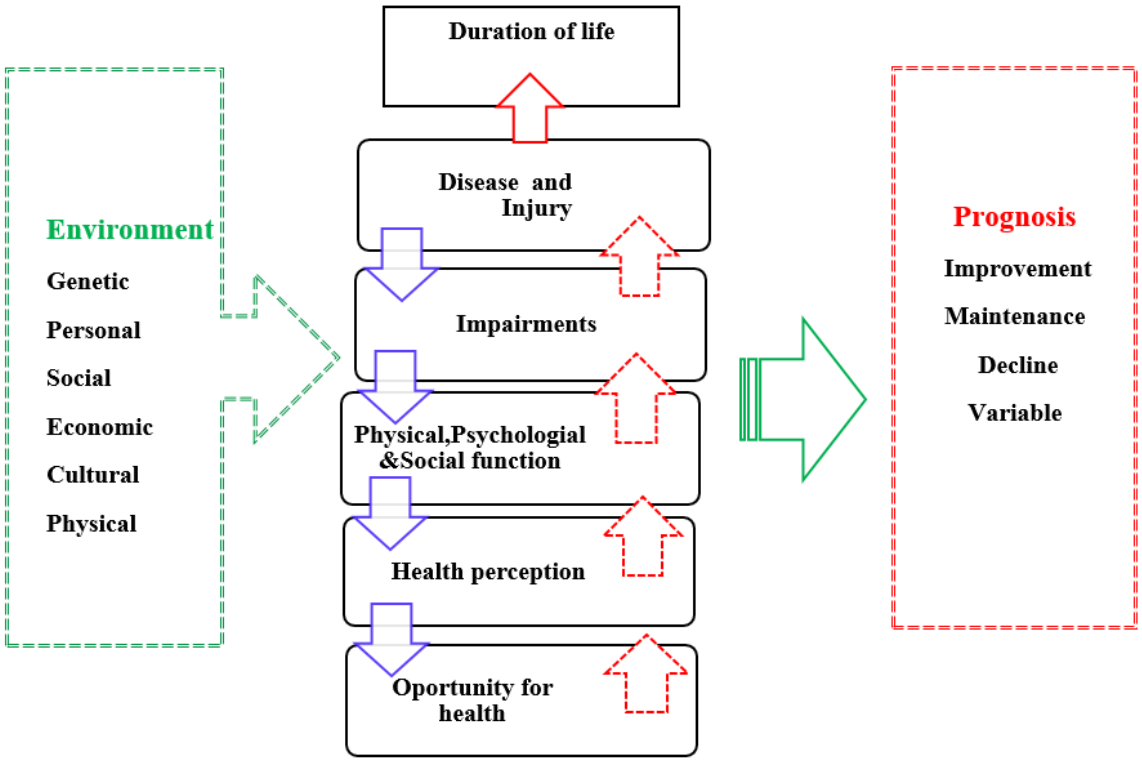


Figure 1.2 Theoretical relationships among HRQoL components adapted from Patrick and Bergner conceptual frameworks (6). [Reproduced with the permission of the editor of *Annual Review of Public Health*]

In 1995, Gift and Atchison (18), discussed the impact of oral and dental health diseases on human well-being and highlighted the need for the conceptualization of OHRQoL. Subsequently, they adapted Patrick and Bergner's conceptual model of HRQoL (6, 18, 34) and introduced the OHRQoL framework and its five dimensions, as shown in Figure 1.3.

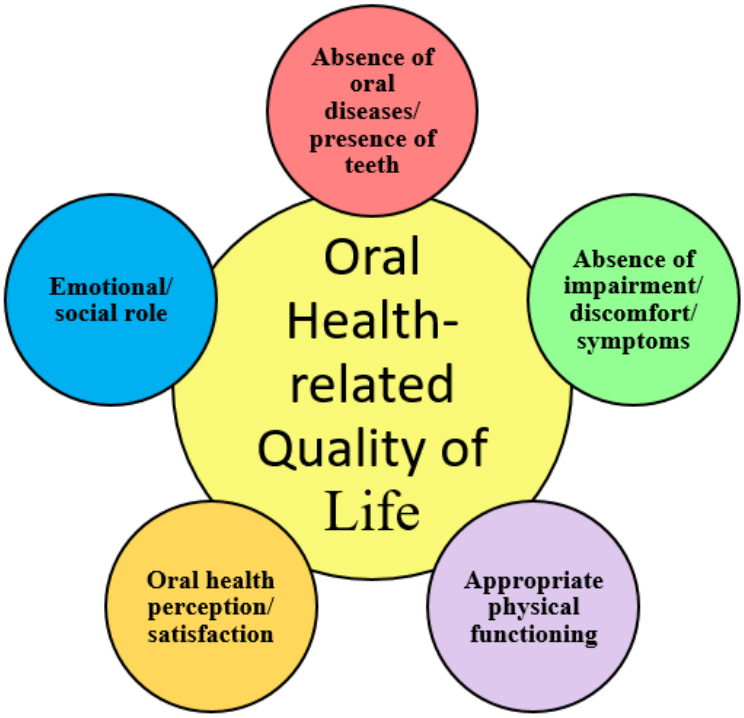


Figure 1.3 Dimensions of OHRQoL according to the Gift and Atchison framework (18, 19).

According to Gift and Atchison (34), OHRQoL "*incorporates survival (absence of oral cancer, presence of teeth), absence of impairment, disease, or symptoms, appropriate physical functioning associated with chewing, swallowing, and absence of discomfort and pain, emotion functioning associated with performing normal roles, perceptions of excellent oral health, satisfaction with oral health and absence of social or cultural disadvantage due to oral status*."

Finally, in the 21st century, the concept of OHRQoL became more popular in the field of dental research and several definitions appeared in the literature:

In 2000, Locker *et al*. defined OHRQoL as: "*The extent to which oral disorders affect functioning and psychosocial well-being*" (35). The U.S. Surgeon General's Report on oral health stated that OHRQoL is "*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*" (36, 37).

Later, in 2002, Locker *et al*. broadened the definition of OHRQoL and defined it as "*Symptoms and functional and psychosocial impacts that emanate from oral diseases and disorders*" (38).

In the same year, Inglehart and Bargamian et al. defined OHRQoL as: "an individual assessment of how the following affect his or her well-being: functional factors, psychological factors, social factors and experience of pain/discomfort in relation to orofacial concern." (30).

1.2.2 Conceptual models of oral health-related quality of life

In 1976, Cohen and Jago (39) developed a conceptual framework to explain the relationship between oral health status and general health aspects, including social well-being. This framework significantly contributed to the development of an instrument for OHRQoL assessment (19, 40). In 1988, David Locker (41) used WHO's international Classification of Impairment, Disability and Handicap (42), and Smith & Sheiham's study (43) on the effect of oral conditions on older people, to propose a conceptual framework for OHRQoL. As shown in Figure 1.4, in this model Locker illustrated various pathways by which oral disorders could affect human overall health and well-being (31, 41).

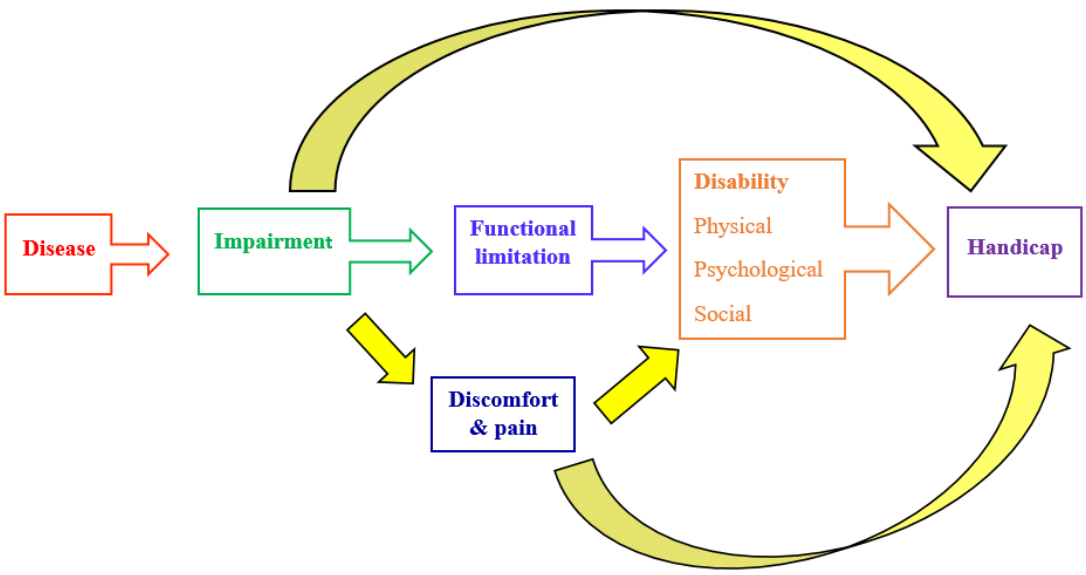


Figure 1.4 Conceptual framework of OHRQoL adapted from Locker 1988 (41).

Later, Locker (44) recommended adopting Wilson and Cleary's framework (45) of HRQoL models to broaden the conceptual model of OHRQoL (44, 46). Wilson and Cleary's model provides the simplest and most comprehensive model to explain the correlation between biological factors and their functional and psychological outcomes. Also, it shows the impact of medical and non-medical factors on overall quality of life (31, 47). Subsequently, all these aspects were observed to have a significant impact on an individual's quality of life as shown in Figure 1.5 (44).

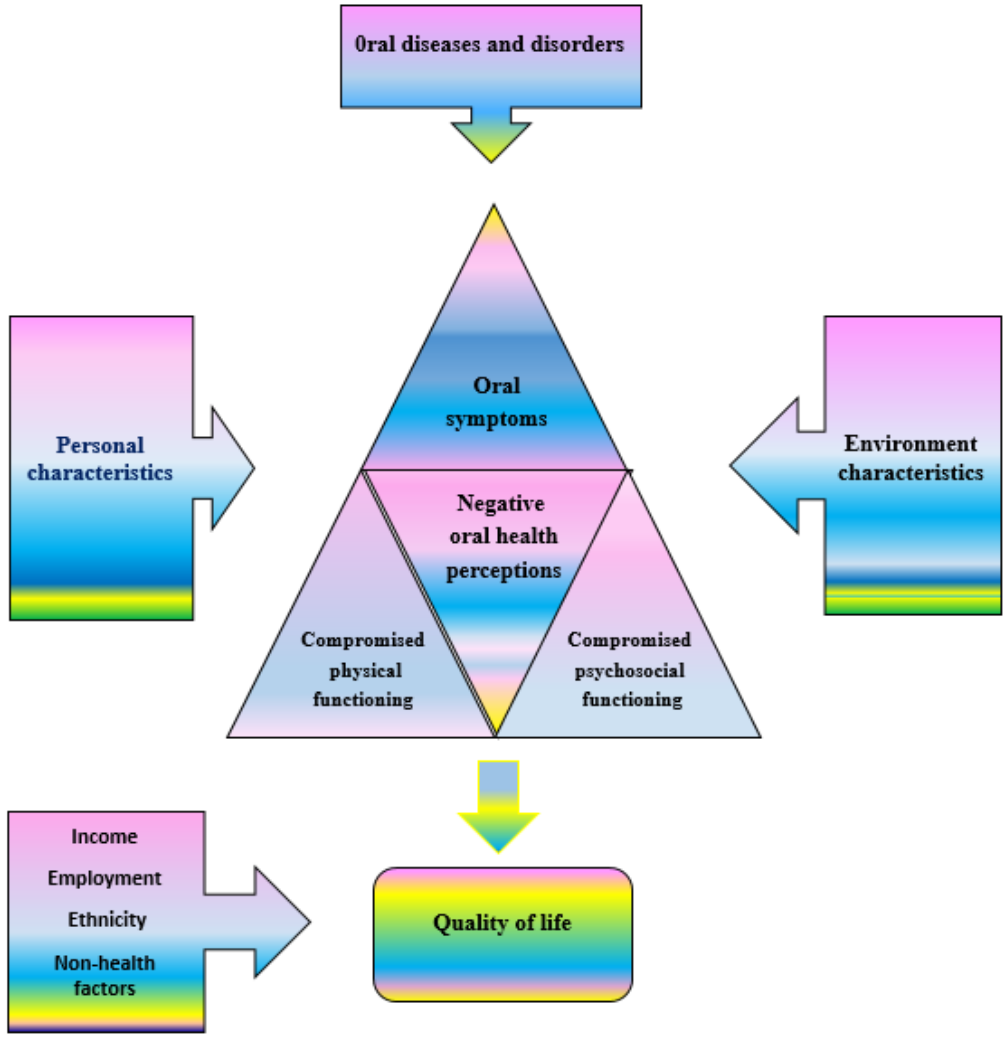


Figure 1.5 The Combination of Locker framework of OHRQoL (2004) and the Wilson and Cleary framework of HRQoL (1995) (44).

1.2.3 Assessment of Health and Oral Health-Related Quality of Life

For a more detailed and accurate understanding of the effect of oral conditions on human well-being, two types of instruments can be used: generic and disease-specific instruments (48, 49).

Generic instruments: These instruments have an effective psychometric property and cover a broad range of health issues. Many instruments have been developed to assess HRQoL outcomes. The Short Form Health Survey (SF-36) is one of the most valid generic instruments to measure HRQoL. It is a 36-item, self-administered questionnaire encompassing eight health scales, and two component summary scores; the physical component summary score (PCS) and the mental component summary score (MCS). The SF-36 subscales are: physical functioning, role-physical, role-emotional, energy (vitality), emotional well-being, social function, bodily pain, general health (50, 51). However, generic health status measures have low sensitivity, poor validity and lack responsiveness to changes in assessing oral health status and certain other specific diseases (48, 52, 53).

Disease-specific instruments: These instruments have some advantages over generic instruments, because they are more precise, focusing on specific health dimensions, and have fewer items, making them less burdensome for patients to answer. Additionally, they have relatively higher sensitivity and better responsiveness to capture minor health changes in specific situations. For example, the Oral Health Impact Profile (OHIP), which is a specific patient-centred measure, assesses the impact of oral diseases on personal lifestyle, which has been more recently referred to as OHRQoL outcomes (48, 52, 54).

In 1985, before development of an OHRQoL conceptual framework, Reisine (55) used the Sickness Impact Profile (SIP) to assess the impact of dental conditions on work absence, social life and daily functioning such as eating, sleeping. This instrument is a generic measure of general health; while it may assess some oral issues such as oral pain outcomes, it is not sensitive to all oral issues, including tooth loss and edentulism (41, 48).

Later on, different studies were piloted to develop valid, reliable and responsive OHRQoL measures (48, 56). These instruments varied in the number of items included, the format (either open-ended or close-ended questionnaire) or the type of response (VAS score or Likert); these variations were due to factors such as the situation in which they were administered, and the target population (31).

Not all existing instruments fulfill OHRQoL aspects (54), and some do not focus on the targets that draw attention on the person's perceptions with regard to various oral conditions, and the impact of these issues on their daily life (31).

Slade (56) specified three instruments to assess OHRQoL: societal indicators, the overall self-rating of OHRQoL and a multiple-item questionnaire. The choice between these instruments depends on the target population, research question and study design (56).

The social indicators of OHRQoL are useful to measure the impact of oral disorders on a large community and particularly among a vulnerable group; for example, to estimate the total number of lost work days or days of restricted activity because of the burden of oral disease. However, this instrument has a limitation when used to assess OHRQoL because many people in society do not work, while for most others, work days were likely to be lost because of preventive dental work, or just simple dental treatment (56).

The overall self-rating approach of OHRQoL is based on a single question, such as "*How do you rate your oral health during this year?*" the answer is either via the visual analog scale or categorized on the five-point ordinal scale ranging from excellent to the poor. This method is simple and easy to use, and can detect the positive and the negative impact of oral conditions, so it is an ideal instrument for nationwide surveys (56).

Multiple-item questionnaire instruments are widely used in research studies because of their capacity to cover the different dimensions of OHRQoL and detect the difference between groups. This approach is based on specific questions to evaluate, in greater details, the different aspects of OHRQoL such as the physical and/or social functioning, pain and discomfort, disability and self-esteem. The collected data are summarized as numeric scores. For some questionnaires, such as OHIP, the subscale total scores can be calculated. This approach is used

frequently in epidemiology studies that address specific research questions with small samples (56). Some multiple-item questionnaires are shown in Table 1.1 (48, 56).

Table1.1 Instruments measuring OHRQoL (48, 56)

	Name of Measure	Dimension measured	No. of items	Response format
Cushing et al, 1986	Social Impacts of Dental Disease	Chewing, talking, smiling, laughing, pain, appearance	14	Yes/No
Atchison and Dolan, 1990	Geriatric Oral Health Assessment Index	Chewing, eating, social contacts, appearance, pain worry, self-esteem	12	6 categories ranging always-never
Strauss and Hunt, 1993	Dental Impact Profile	Appearance, eating, speech, confidence, happiness, social life, relationship	25	3 categories: good, bad, no effect
Slade and Spencer, 1994	Oral Health Impact Profile	Function, pain, physical disability, psychologic disability, social disability, handicap	49	5 categories ranging: very often-never
Locker and Miller, 1994	Subjective Oral Health Status Indicators	Chewing, speaking, symptoms, eating, communication, social relations	42	Vary with question format
Leao and Sheiham, 1996	Dental Impact on Daily Living	Comfort, appearance, pain, daily activity, eating	36	Vary with question format
Adulyanon and Sheiham, 1997	Oral Impacts on Daily Performances	Performance in eating, speaking, oral hygiene, sleeping, appearance, emotion	9	Vary with question format

In 2007, Locker and Allen (54) established a guideline to appraise the validity of OHRQoL instruments, and reviewed five of those most frequently used. In all these instruments,

they found that the OHIP has the most significant association with the patient's life satisfaction and could detect the impact of oral conditions on overall health and quality of life, even after controlling predictors' variables (54).

OHIP was first developed and validated in 1994 by Slade and Spenser (57). This measure can detect the amelioration and decline in health conditions; thus it is useful in clinical studies (58). The OHIP measure is based on the Locker conceptual framework of OHRQoL and WHO International Classification of Impairments, Disabilities, and Handicaps. It is a multi-item questionnaire divided into seven subscales: functional limitations, pain, physiological discomfort, physical disability, psychological disability, social disability and handicaps (56). Evidence shows that OHIP has high psychometric properties for internal reliability (Cronbach's alpha=0.70-0.83), stability (inter-class correlation coefficient=0.42-0.77) and construct validity (57). OHIP is available in several translated language versions (59).

Several versions of OHIP have been developed sequentially and translated into different languages: the full version (OHIP-49), the short version (OHIP-14), the OHIP-EDENT and OHIP-20 (58-60).

OHIP-49: The original version (OHIP-49) is a self-administered closed questionnaire. Participants are asked to answer each question by using a 5-point Likert-type scale, ranging from 0 to 4 (never=0, hardly ever=1, occasionally=2, fairly often=3, very often=4). The higher scores are associated with negative impacts on OHRQoL (48). With its 49 items, OHIP-49 requires a long time to complete, which is considered a major limitation in clinical research. In addition, since some included items are not relevant to edentulous people, OHIP-49 is not valid in edentulous population. Furthermore, the order in which the participant answers the questionnaire may affect the results, indicating a weak construct validity(61).

OHIP-14: To reduce administration time, Slade (62) eliminated some items from the original model and developed a shortened version (OHIP-14), which contains 14 items. In spite of the great reduction in number of items, OHIP-14 covers the seven OHRQoL subscales it is still a valid and reliable instrument to assess OHRQoL among dentate people (48, 62-65). However, OHIP-14 is not appropriate for edentulous patients, because it does not contain items

related to prosthesis and masticatory issues; this affects its construct vitality when used for clinical studies among the edentate population (65).

OHIP-EDENT: To overcome the limitations of previous OHIP models, Allen and Locker (65) developed the OHIP-EDENT. OHIP-EDENT is a shortened version derived from both OHIP-49 and OHIP-14 and it contains 19 items. OHIP-EDENT is more appropriate than OHIP-14 to assess OHRQoL in edentulous patients, and is as sensitive as OHIP-49 in detecting changes in OHRQoL scores caused by prosthodontic intervention (65).

OHIP-20: OHIP-20 is a specific and self-reported instrument, developed by adding a twentieth question to OHIP-EDENT in order to fully encompass the requirement for complete edentate patients (60, 65, 66). This version consists of 20 items grouped in 7 subscales: 1-functional limitations (3 items), 2-physical pain (4 items), 3-psychological discomfort (2 items), 4-physical disability (4 items), 5-psychological disability (2 items), 6-social disability (3 items),7- handicap (2 items) (67). These items are scored on six-point Likert-type scales (never=1, rarely=2, occasionally=3, often=4, very often =5 and always=6). The total scores are ranged from 20 to 120, **with the lowest scores indicating excellent OHRQoL outcomes** (68).

The OHIP-20 seems to be a valid and reliable instrument in geriatric studies when used to assess patients' outcomes regarding the impact of prostheses on the physical, social and psychological aspects of their quality of life (66, 69, 70). In fact, the shortened version of OHIP-20 has a good responsiveness when used for edentulous patients(71).

1.3 AGING, EDENTULISM AND ORAL HEALTH-RELATED QUALITY OF LIFE

1.3.1 The impact of aging on health-related quality of life

In the twenty-first century, global life expectancy has significantly increased due to the aging of baby boomers and the decline of mortality rates across the world (72, 73). The population aged 60 years or over increased from 8% in 2012 to 8.5% in 2015, and is expected to grow faster in the next decades, to reach 16.7% by 2050 (72, 74).

In Canada, according to the 2016 Census (75), life expectancy increased rapidly, and exceeded 82 years at some point between 2011 and 2016. The census data showed that people aged 65 years and older comprise 16.9% of the overall Canadian population and is expected to reach 23% by 2031. Data from Canada Census 2016 showed that the proportion of seniors in Quebec rose to 18.3% between 2011 and 2016, which is higher than the national rate (16.7%) (75).

However, having a long life does not always mean having a healthy life, as explained by Richard J Hodes, (76), the director of the [U.S.] National Institute on Aging, part of the National Institutes of Health. In a study produced by the U.S. Census Bureau he stated: "*People are living longer, but that does not necessarily mean that they are living healthier. The increase in our aging population presents many opportunities and also several public health challenges that we need to prepare for*." (76)

Chronological aging is an inevitable and gradual process, accompanied by biological and physiological changes that may affect all body systems. The average deterioration in organ function, after the third decade of age, is approximately 1% per year, which in turn, has a negative impact on the elderly lifestyle (77).

Moreover, aging contributes to increasing the prevalence of numerous chronic diseases such as sleep apnea, obesity, systolic hypertension, heart failure, diabetes (5, 78-85). The presence of certain chronic diseases and the side effect of some related treatments and medication can lead to poor life satisfaction, lack of sleep quality and a significant deterioration in all dimensions of elders' quality of life (86, 87). The severity rate of all geriatric alterations may vary greatly among the elderly, and is influenced by several factors, such as socio-economic status, environment, lifestyles, genetics, systemic diseases, medication and ability to maintain good personal oral hygiene (1, 88, 89).

Several studies showed that sleep troubles in the elderly are often due to existing geriatric diseases and not related to aging per se; in turn, poor sleep quality could have a negative impact on quality of life and may affect sleep patterns (85, 90-92). These findings echo an Emami *et al*. study (93) that showed that sleep disturbance can be associated with depression, somnolence,

a decline in functional performance, deterioration in life satisfaction, all of which result in impairment in elders' quality of life.

1.3.2 Impact of aging on oral health and oral health-related quality of life

Aging-related changes also affect the oral cavity, leading to progressive and inevitable physiological changes in the soft and hard tissues, and decline in several oral functions such as reduction in the strength of the masticatory muscles, tooth erosion, gingival recession, decline in salivary gland function, periodontal attachment loss, tooth loss, etc. (1, 88, 94).

Furthermore, some systemic diseases in the elderly and their related treatment contribute to increasing the risk of some oral diseases, such as xerostomia, root surface caries, severe periodontal diseases, and oral lesions. Accumulation of these oral health-related issues throughout the life span may raise the risk of tooth loss (83, 88, 95-97).

A British survey (98) showed that dental and oral diseases have a notable effect on quality of life in elders, with the highest prevalence reported among edentate people; in this survey researchers highlighted a strong association between the total numbers of lost teeth and the patient's ability to fulfill basic daily tasks, particularly speaking and eating some kinds of food. On the other hand, the impact of oral conditions on other aspects of elderly life, such as physical functioning, sleeping, social interaction, was reported less, but when it happened it was severe (98).

In 2012, a Canadian cross-sectional study (73), involving 1461 adults aged 45 years or over living either in long-term care facilities (LTC) or in the community, found that 25% of the elderly reported significant impact (fairly/very often) on one or more aspects of OHRQoL, with the greatest effects being within the "physical pain" and the "psychological discomfort" dimensions (73).

Furthermore, oral health conditions and patient satisfaction seem to be strong predictors of OHRQoL in the elderly, regardless of the number of remaining teeth (70, 99). Thus, improvement in oral health conditions in the elderly was accompanied by a rise in both self-esteem and productivity, resulting in recovery of psychosocial life and improvement in overall OHRQoL scores (99).

1.3.3 The impact of tooth loss on oral health and oral health-related quality of life

The last decades have shown a great decline in tooth loss rate in most countries around the world (100). This phenomenon is offset partly by global population aging, which contributes to maintaining relatively high numbers of edentulous, older people, and leads to the persistence of edentulism as one of the burdensome diseases that still affect a larger number of human lives around the world (101, 102).

The prevalence of tooth loss varies across and within countries, and tends to be lower in developed countries (103, 104). In the United States, the edentulous population is expected to be around 8.6 million people in 2050 (105). A Canadian survey in 2007–2009 (106) showed the average rate of edentulism was nearly 4% for people aged 40–59 years; this proportion increased to 22% among elders aged 60–79 years, and it is often associated with low socio-economic status (107).

Edentulism rates increase progressively with age and tend to be higher among elders who have chronic diseases, lower education levels, poor economic status, and poor oral hygiene (103-105, 108).

Edentulism is associated with several anatomical and functional alterations in the oral cavity affecting chewing capacity and facial appearance which accordingly has a negative impact on OHRQoL (5, 109, 110). Following tooth loss, the mandible loses occlusal support and its functional pathway to the proper position, which leads to decline in the vertical dimension of occlusion (VDO), a decrease in the height of the lower face and relative mandibular prognathism (111-113). In the mandibular rest position, the mandible counterclockwise and shifts forward during swallowing and backward in the supine position (69, 112). The tongue is retracted and enlarged to fill the place of the missing teeth in the resting and functioning position, the soft palate moves toward the posterior wall of the pharynx, reducing the patency of the upper airway (69, 114). Therefore, edentulism may lead to a significant increase in the collapsibility of the upper respiratory tract and raises the risk of sleep apnea, especially among elderly people (69, 115).

Moreover, the mass and strength of the masseter muscle are decreased after complete tooth loss, which manifests in a decline in the masticatory forces and development of chronic mouth breathing (4, 8). Breathing mostly through the mouth reduces the retro-glossal and retro-palatal space, and shortens the distance between the position of the hyoid bone and the mandible, which decrease the upper airway flow rate (8, 116). The decline in the mastication function makes the majority of edentate people (even those who wear complete dentures) avoid eating some kinds of essential food with high nutritional value such as meat, certain fruits and raw vegetables, carbohydrates, nuts, etc., and replacement with high-fat meals of low nutritional value that are easy to chew and swallow. This increases the risk of malnutrition and contributes to the development of several health problems such as obesity, diabetes, cardiovascular diseases, which have a harmful effect on general health and well-being (117-119).

Furthermore, the aesthetic, phonetic and physiologic alterations associated with edentulism often lead to impairment in oral functioning and pose a socio-economic weight on individuals and communities around the world (1-3, 77, 103, 110). These alterations present serious challenges which must be met by the elderly in order to maintain good oral health and appropriate well-being (120).

Some studies found strong interrelation between tooth loss, general health, and quality of life, and reported a negative impact of edentulism on more than one aspect of OHRQoL (5, 103, 107).

The impacts of edentulism on OHRQoL can be explained partly by the progressive resorption of the residual alveolar ridge and the reduction of the volume of the supporting tissues which result in:

1. Declines in the stability and retention of complete dentures, especially in the mandible jaw, which could lead to pain, discomfort and traumatic ulcers (121).

2. Decreases in the VDO (122), increasing mandible prognathism and a change in the facial appearance (122).

3. Deterioration in the proper functioning of dentures regarding mastication performance, clarity of speech, laughing, which causes restriction to some social interaction (121, 123).

The causality of the decline in OHRQoL among edentulous elders has not been fully clarified yet, but many studies have pointed out a link between patients' satisfaction with their dentures and other variables such as denture quality, oral health history, patient perception and the socio-demographic characteristics of the patient (70, 124-126).

1.3.4 Impact of wearing dentures and on oral health-related quality of life

Despite advances in prosthodontic technology which can repair some orofacial function, no dental prostheses can fulfill all the functions as the natural dentition, including chewing functioning, the way of speaking, as well as the impact on facial appearance (127-131). It has been estimated that more than 45% of denture wearers manifest at least one disease induced by oral pathogenic species (132, 133), with higher prevalence found among women than men, and it is strongly related to nocturnal wear of prostheses as well as improper oral and denture hygiene care (12, 133-138).

Results of several studies showed that poorly fitted prostheses give rise to several oral problems, such as stomatitis, cheilitis, traumatic ulcers, food accumulation, and halitosis, which in turn gives rise to unpleasant sensation or pain (10, 139-141). These denture-related diseases are often associated with stress, discomfort, physical pain, and restriction on the ability to fulfill certain daily activities (eating, kissing, smiling, etc.) (142, 143).

Moreover, several studies reported a strong association between OHRQoL and patients' satisfaction with their prostheses regarding, pain, comfort, functioning and chewing ability some studies concluded that patient's satisfaction with regard to oral health is a strong predictor of OHRQoL among denture wearers (70, 125, 128, 144, 145).

Whatever the hidden reasons, it seems that elderly who are not satisfied with their dentures (regardless of whether the dentures fit), also have poor social interaction and are more likely to report impaired OHRQoL (146-149). The cumulative effects of all the above-mentioned factors could affect self-esteem among denture wearers, who worry about being rejected by the community. Thus, some seniors become relatively depressed and tend to withdraw from social gatherings, which could lead to impairment in their OHRQoL (148, 150, 151).

1.3.5 Impact of nocturnal wearing of the prostheses on oral health-related quality of life

Continuous wearing of complete dentures causes an alteration of the environment of the oral cavity and favors conditions for the development of some opportunistic infectious diseases (138, 152).

Two principal factors contribute to this alteration, the first one is related to the rough inner surfaces of dentures that act as a reservoir for multi-species of oral biofilm microorganisms, and provide optimal conditions for bacterial colonization and oral biofilm formation in the oral cavity, including on denture surfaces, tongue and oral mucosa (12, 153). The second factor is that the denture base creates a barrier against saliva flow and inhibits good oxygenation of the underlying mucosa. Thus, continuously wearing dentures may inhibit the proper cleaning effect of the tongue and reduce the effect of the buffering capacity of the saliva (154).

This alteration leads to a decline in pH value of oral mucosa and provides favorable acidic conditions for retention of oral debris and overgrowth of opportunistic pathogens, which consequently raise the prevalence of some inflammatory and denture-related diseases such as denture stomatitis, angular cheilitis, traumatic ulcers, papillary hyperplasia, and unpleasant breath smell (133, 135, 141, 154-156).

In addition, along with other factors including poor oral hygiene, denture stability, aging, diabetes and the presence of immunologic disorders, the continuous wearing of dentures may trigger inflammation reactions that lead to life-threatening disorders such as respiratory infection and endothelial dysfunction and could raise the risk of oral carcinoma (12, 157-159). The predominant opportunistic pathogens isolated from the oral cavity in seniors are Candida albicans (136, 141, 160), streptococcal species (12), and halitosis-related bacteria (155).

Therefore, in 2009, the American College of Prosthodontists (ACP) (161) established evidence-based guidelines for the care and maintenance of complete dentures. These guidelines recommend avoiding wearing prosthesis 24 hours per day, and daily brushing and rinsing of dentures to prevent the accumulation of several Candida microorganisms (particularly Candida albicans) and Gram-negative anaerobes (161).

Despite ACP recommendations, many edentulous elders refuse to remove their dentures at night since that may affect their self-confidence regarding their relationship with a partner, and they believe that taking out the prosthesis has a negative impact on emotional feeling and sexual behavior, as was explained by some patients: *"A man would not want to kiss a woman with her teeth out." "It makes me nervous to sleep without the dentures … cannot relax with dentures out and don't want anyone, not even my husband, to see me without my dentures"* (162).

The positive impact of sleeping with dentures on psychological and social aspects of OHRQoL was noted in a pilot study that assessed the effect of nocturnal wearing of the prosthesis on OHRQoL outcomes in 13 edentulous elders patients (163). This pilot study concluded that there was no significant difference in global OHRQoL scores between wearing and not wearing dentures during the night. However, it was found that elders who slept with dentures were more likely to have better outcomes scores in two dimensions of OHRQoL: psychological disability and social disability, in contrast to the other three dimensions (functional limitation, physical pain, physical disability) that showed impaired scores (163).

1.3.6 Impact of sleep quality on HRQoL and OHRQoL

Epidemiological evidence shows that the quality and the quantity of sleep decrease with age (164-166). It is estimated that more than 50% of elderly complain of sleep disturbance, with the prevalence slightly higher among women (166, 167). The sleep disturbance symptoms most commonly reported in elderly adults are difficulty in falling asleep or waking up, insomnia, diurnal sleepiness, abnormal sleep and irregular sleep patterns events, parasomnias, and breathing disorders, including snoring and obstructive sleep apnea (OSA) (168). Some of these symptoms become bothersome not only for patients but can also disturb the sleep of the bed partner, leading to poor quality of sleep for both of them (87, 90, 168).

Numerous studies showed sleep disturbance is not a normal result of aging per se, but, instead, often interacts and is synchronized with other pre-existing geriatric chronic diseases and/or their treatment (167, 169, 170). Accordingly, sleep disturbance could be a primary sleep disorder when it is attributed to neurological system disorders including OSA, or it could be a secondary sleep disorder, when it is triggered by certain medical morbid conditions such as

depression, oral issues and edentulism. Or it could be related to poor sleep habits such as wearing dentures at night and sleeping in a supine sleeping (93, 171, 172). Whatever the etiology of sleep disturbance, poor sleep quality must be taken seriously because it can be an early sign of health issues that may impede life and well-being (93).

The most common symptoms of sleep deprivation are depression, excessive daytime sleepiness (173), physical disability and deterioration in daily functioning (174, 175), cognitive impairment (176), and high incidence rates of vehicle collisions and work injuries (177, 178). Furthermore, insufficient sleeping may be associated with some morbidity and mortality health problems, including hypertension, heart attack, depression, respiratory disorders, obesity (179).

Recent studies show that poor sleep quality has a negative effect on two components of HRQoL (PCS and MCS) and could be a predictor of impaired HRQoL (180-183). In fact, seniors who have poor sleep quality (regarding night sleep duration, sleep patterns, sleep onset latency) may have good general health scores but impaired HRQoL outcomes, which can be manifested by a decline in physical functioning, deterioration in cognitive performance, pain intolerance, depression and consequent restrictions in social activities (180, 184-190).

On the other hand, the U.S. Surgeon General's Report on oral health has shown that oral diseases can adversely affect the quality of sleep in edentulous elderly and result in deterioration in their OHRQoL (37). In fact, sleep disturbance could be a secondary disorder of tooth loss in elders when it has been triggered by denture-related problems such as pain, discomfort, halitosis, difficulty breathing, or could be linked to craniofacial alterations associated with total tooth loss, which contributes to sleep-disordered breathing including snoring and OSA (8, 172). Therefore, the cumulative effects of chronic oral issues may disturb nighttime sleep leading to impaired OHRQoL in edentulous elders (93).

1.4 OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA) is a sleep disorder more often seen among the elderly which has a severe impact on sleep quality and OHRQoL, especially among the elderly (93, 191). The Canadian Health Measures Survey (CHMS) (192) reported that in 2016–2017, 6.4% of all Canadians suffered from OSA, with a higher incidence (around 13%) reported among older adults (aged 40–79); 25% of the elderly (aged 60–79) have a high risk of OSA. This ratio

is much higher than the 3% of adults reported from the 2009 Canadian Community Health Survey (192, 193).

1.4.1 Definition, diagnostic and symptoms

OSA is caused by the relaxing of upper airway muscles, which results in narrowing and/or collapse of the upper airway during sleep, leading to impairment of pulmonary gas exchange, oxygen saturation, hypercapnia, temporary cessation of breathing, arousal from sleep and disturbance of the night's sleep (194, 195).

The majority of patients with sleep apnea are unaware of the disorder, which is often observed by the bed-partner or family members due to the accompanying symptoms, including frequent snoring, cession of breathing, and choking leading to awakening (196).

The standard diagnostic of OSA is performed by the overnight polysomnography test which assesses the respiratory events (Apnea/Hypopnea) per hour recorded during sleep. The severity of OSA is based on the apnea/hypopnea index (AHI) (197), as follows:

AHI <5 : No OSA

AHI =5-15 : Mild OSA

AHI =15-30 : Moderate OSA

AHI >30 : Severe OSA

Patients who suffer from OSA also complain of several symptoms such as tiredness, diurnal sleepiness, morning headaches, energy deficiency, poor attentiveness, excessive daytime sleepiness and attention deficiency (198, 199). Daytime sleepiness and attention deficiency are associated with increased risk of road traffic collisions and doubling the risk of work-related injuries (199-201).

Furthermore, OSA is a risk factor for several morbidity and mortality systemic diseases such as cardiovascular diseases, hypertension, type 2 diabetes, diabetic kidney diseases, stroke (202-205). OSA may also contribute to the development of cognitive and memory dysfunctions in the elderly, these troubles are manifested by symptoms such as depression, memory retention, and Alzheimer disease (206, 207).

1.4.2 Pathophysiology and risk factors

Epidemiology studies reveal several underlying anatomic and non-anatomic factors that affect the patency of the human pharynx and contribute to the development of OSA (196, 208). Airway patency may also be triggered by alterations in oral and maxillofacial structures such as total tooth loss (115). Evidence also shows that the prevalence of OSA is strongly influenced by age, gender, body mass index (BMI), genetic factors, smoking, alcohol and drug consumption (195, 196, 208-210).

1.4.2.1 Aging and gender

In both sexes, OSA progressively increases with age (211). The prevalence among the elderly (≥65 years) is 2–3 times greater than that for adults aged 30–64 years old (191). The impact of aging on OSA may be explained by age-related alteration in the airway structures, including an increase in the fat mass in the pharyngeal area, divergence of the soft palate, deterioration in the elastic properties of the lungs, and a decline in the functioning of upper airway dilator muscles (195, 196).

An MRI-based research study reported that the length of the soft palate increases significantly with age, as does the thickness of the para-pharyngeal fat pads, independently of gender and BMI (212). In addition, several aging factors may increase the collapsibility of pharynx, such as deterioration in the reflex of the pharyngeal dilator muscles (genioglossal muscle), decrease of respiratory stimuli (hypercapnia and hypoxia), decrease in the mucosal sensory threshold in the upper airway and an increase of negative intra-pharyngeal pressure, especially during sleep, which may aggravate the risk of OSA (212, 213).

On the other hand, population-based prospective studies (209) reported that men are more likely to suffer from OSA than women (3-4% versus 2%), but this ratio tends to decrease after menopause (196, 209). The higher prevalence of OSA among men could be explained by anatomical and physiological differences. For example, adult men have larger fat deposits around the upper airway, mainly at the palatal level, and have bigger tongues, larger soft palates, and longer upper airways compared to adult women (214, 215). Other gender-related differences could influence OSA prevalence, including the protective effect of female hormones on the

pharyngeal dilator muscles (209, 216), increased ventilation response to arousal and the higher waist-hip ratio in men (217, 218).

1.4.2.2 Obesity

Obesity is an excessive body fat accumulation assessed by BMI to be equal to or greater than 30 kg/m2 (219). Obesity is considered one of the major risk factors for OSA all over the world (196, 208, 220). Increasing BMI appears to be strongly associated with increasing the prevalence and severity of OSA (221, 222). Likewise, losing weight, either by surgical or by non-surgical intervention, is associated with a significant decrease in the AHI, and improvement in OSA outcomes (223, 224).

The obese person tends to have a larger neck circumference and greater deposit of fat around the pharynx compared with a normal person (208). Excessive fat deposition, particularly in the posterior of the tongue and retro-lingual airway, results in narrowing of the pharyngeal lumen, decreased oxygen saturation; it may also contribute to impairment of the protective effect of dilator muscles and raise the risk of upper airway collapse which has great impact on the severity of OSA (208, 222, 225, 226).

Furthermore, abdominal circumference and waist-hip ratios have a significant effect on lung functioning, and are strong predictors of OSA in the elderly (221, 227, 228). Fat pads around the abdominal area and trunk could impair normal breathing by different mechanisms including restricting movement of the diaphragm and chest, decreasing lung volume, and reducing functional residual capacity. Together these changes may enhance the pharyngeal collapsibility, especially during sleep (225, 228).

1.4.2.3 Anatomic factors

The abnormal anatomic feature of the upper airway applies passive closing pressure on the upper airway, which could be a critical factor in the development of OSA (229). Several computed tomography imaging studies report a higher incidence of OSA among patients who have narrow upper airways in the lateral dimension compared to others with an elliptical airway shape (230-233).

In Jose E. Barrera *et al*.'s study (234), cephalometric and MRI techniques were used to compare the upper airway diameter, length of the soft palate and tongue volume in apneic patients with these measurements in non-apneic patients. Results showed that apneic patients tend to have larger tongue volume, narrower airways in both the mandibular posterior airway space (PAS) and the nasal PAS; but no significant difference was reported in the occlusal PAS diameter or in the length of the soft palate (234).

Other anatomic factors that may affect the oropharynx patency and compound the severity of OSA are: increased airway length (233), enlarged tonsils (235), retruded position of the tongue with higher grade (Grade IV) in Friedman and Mallampati classifications (236), a lower position of the hyoid bones and greater distance between the mandibular plane and the hyoid bones (MP-H) (237).

1.4.2.4 Non-anatomic factors

OSA may be caused by non-anatomic factors, such as reduced pharyngeal dilator muscles responsiveness, low arousal threshold, and high loop gain, which are found in 56% of patients with OSA (229). Genetic factors are also considered to be great contributors to the incidence and severity of OSA, and that could be the main reason explaining the differences in the OSA rate among multi-ethnic populations across the world (191).

In fact, during wakefulness, the pharyngeal dilator muscles reflex (particularly of the genioglossus muscle and tensor palatine) offset the harmful effect of compromised anatomical structures of the upper airway among apneic patients. This maintains patency of the upper airway; consequently most apneic patients have normal respiration in the daytime (208). However, during sleep, the activity of the pharyngeal dilator muscles is reduced significantly, which is associated with repetitively pharyngeal collapses, and repetitive apnea and hypopnea events (238).

Moreover, the mandible jaw in a patient with OSA has shown greater movement downward and backward to allow mouth breathing during sleep, the tongue is retracted which contributes to pharyngeal collapse during sleep (239, 240).

On the other hand, some daily lifestyle habits, such as cigarette smoking and regular alcohol consumption, are other possible factors that may worsen OSA among the elderly with OSA (191, 196).

1.4.2.5 Edentulism

Evidence suggests that edentulism could significantly increase the risk of OSA in adults, and may be considered an independent risk factor for this disease (8, 115). USA. study (8) estimates that the prevalence of OSA is 61% greater among American edentulous persons aged 25–65 years compared to the dentate, but this prevalence does not seem to be similar in the elderly (8).

Tooth loss is associated with resorption of the residual alveolar ridge and anatomical alteration in the craniofacial structure; These alterations may have a significant impact on airway patency (115). These alterations are manifested by mandible rotation forward and upward, loss of the VDO, and consequently a decrease in lower face height and a pseudo-prognathism appearance (69, 112). In most edentulous patients, the tongue has been observed to be wider and is retracted in the rest position, and the neuromuscular functioning of the pharyngeal dilators muscles are impaired, which increases the risk of upper airway collapse (115, 241, 242). Masseter muscle strength is reduced after tooth loss, which enhances chronic mouth breathing among the edentulous. Breathing through the mouth leads to a decrease in the mandible-hyoid bone space (MP-H), and narrowing of the retro-palatal and retroglossal areas, which raise the prevalence of OSA (8).

1.4.3 Impact of nocturnal wearing of prostheses on sleep apnea

The impact of nocturnal wearing of complete dentures on OSA is still controversial, and several studies have been conducted to comprehend this relationship. In 1999, Bucca *et al*. (243), compared two nights of polysomnography recording for 6 OSA elderly persons: in the first night they wore prosthesis while sleeping, and in the second they did not. Results showed sleeping without dentures was associated with a significant increase in AHI, a decrease in anteroposterior oropharyngeal wall distance, and a decline in arterial oxygen saturation. These results concur closely with another study, conducted by Bucca *et al.* (115), which showed that sleeping without

dentures was associated with significant decreases in the retro-pharyngeal space, increases in the morning level of both exhale nitric oxide and oral nitric oxide (p=0.001), indicating a decrease in airflow rates during the night, and increases in AHI (115). Similarly, Arisaka *et al*. (244) reported an improvement in AHI among most apneic patients (27 of the 34 patients) when they slept with their dentures.

In addition, several cephalometric analyses show an improvement in retro-pharyngeal space and posterior-anterior space when patients were sleeping with complete dentures with an appropriate VDO (243, 245, 246). Maintaining acceptable VDO during the night contributed to improving upper airway patency, making a favorable change in the position of the tongue and the jaw and consequently reducing the number of apnea/hypopnea events (245). A study by Gupta *et al*. (246) showed that using an acrylic jig 2–3 mm thick could produce an adequate increase in the VDO, improving the respiratory rate and creating a positive impact on OSA patients. Thus, prosthesis could act as a protective oral appliance in edentulous patients with OSA (246). However, this finding contrasts with a study by Chaccur *et al*. (247), which reported that using an intraoral device (IOD) in order to increase VDO without mandible protrusion could reduce snoring events but did not make a significant improvement to OSA parameters.

In a Bucca *et al.* study (248), removing dentures was associated with a significant decrease in the retro-pharyngeal space and a small decrease in airflow rates among edentulous patients. In contrast, Gowda *et al.*(249) did not find a significant effect of nocturnal wear of dentures on both upper airway dimensions, arterial oxygen saturation and diurnal sleepiness.

Another study showed that the protective effect of complete dentures could vary among adults and may be related to the severity of OSA. Almeida *et al.*'s study (15) reported that wearing complete dentures is associated with increasing AHI among elderly with mild OSA (p> 0.005) when they slept in the supine position, but no significant difference was found among the elderly with moderate or severe OSA (p=0.2). However, higher BMI among mild OSA patients in the Almeida *et al.* study (15) could potentially affect the AHI outcomes and may bias the results.

In 2013, Emami *et al*. (250) conducted a longitudinal cohort study enrolling 172 elderly edentulous patients to evaluate the effect of nocturnal wear of the prosthesis on sleep quality,

diurnal sleepiness, and OHRQoL. Results based on a series of assessments during a two-year follow-up showed a slight decline in the quality of sleep among participants who slept with their prosthesis, but this effect was not statistically significant. These results are consistent with results from a pilot randomized crossover clinical trial study (163), which showed a negative impact of nocturnal wear of complete dentures on sleep quality, strongly related to the severity of OSA, with a higher incidence rate reported among elderly patients with initial AHI≥15 when they slept with their dentures (163).

Recently, Emami *et al*. (14) piloted a systematic review and meta-analysis study of the interrelation between nocturnal wear of prosthesis and sleep quality. Evidence based on ten systematic reviews and five studies included in meta-analysis, showed no significant difference on AHI for sleeping with or without dentures. It is worth mentioning that the heterogeneity in some of the included studies could affect the final results, thus further randomized control trial studies may be required. However, a total of two homogenous randomized control trials were included in this study, and they demonstrated decrease in AHI while sleeping without dentures, but this effect trends toward statistical significance (14).

1.4.4 The impact of sleep apnea on health and oral-related quality of life

Recently, much attention has been directed toward the relation between sleep quality and OHRQoL. A prospective study of 29 patients found OSA had a negative impact on all aspects of HRQoL; it reported an improvement in vitality, social functioning, and mental health outcomes after eight weeks of nasal continuous positive airway pressure (CPAP) therapy and this was strongly related to the degree of the impairment before the intervention (251).

In 2010, a study conducted by Emami *et al.* (93), compared the relationship between sleep quality and OHRQoL scores in the elderly who wear a complete denture. Results showed that the elderly with poor OHRQoL scores also complained of denture problems and reported excessive daytime drowsiness. Also, the negative impact of OSA was seen on all aspects of OHRQoL, with statistically significant difference reported for the functional limitation aspects. However, the possibility of volunteer bias and the fact that self-reported assessment was used could distort the estimation of this relationship and may reduce the validity of this study. Also,

the cross-sectional analysis used in this study could not determine the causal direction between sleep quality and OHRQoL (93).

In 2018, Miki et al. (252) study showed that individuals who have low OHRQoL scores also have poor sleep quality, and a negative correlation was found between PCS and the mental health component summary scores of HRQoL. Here again, the small sample size and the self-reported assessment of this relation could affect the results of this study (252).

To conclude, the contradictory results in the literature regarding the relationship between the nocturnal wear of dentures and health and OHRQoL have elicited further studies to obtain more evidence about this relationship.

CHAPTER 2: METHODOLOGY

2.1 PROBLEMATIC

The association between nocturnal wear of complete dentures, sleep disorders and OHRQoL remains controversial. The literature review has revealed a possible link between sleep quality and quality of life in edentulous patients who wear their prostheses at night (69). Some studies found that the nocturnal wear of dentures have a positive impact on the quality of sleep (115, 245). In contrast, a preliminary study (15) showed that the severity of OSA increased when patients slept with their dentures, whereas a longitudinal study (250) could not detect any significant association between sleeping with dentures and sleep quality.

A pilot RCT study (172) enrolling 13 edentulous elders with OSA showed a negative impact of sleeping with dentures on sleep quality among patients with moderate to severe OSA (OSA), but no significant difference in the daytime sleepiness or quality of life has been found (163). A cross-sectional epidemiology survey of 325 elders (50.9% edentulous) reported a significant relationship between burdensome oral symptoms, including ill-fitting dentures, sore mouth, and dry mouth, and the OHRQoL (11).

Evidence showed that the nocturnal wear of dentures can increase the prevalence of chronic inflammation of the oral mucosa (13, 161), and raise the risk of several other oral issues such as traumatic lesions, prosthetic stomatitis and bone resorption (253-256).

To our knowledge, no confirmed clinical guideline provides evidence-based recommendations to improve the OHRQoL among edentulous elders suffering from OSA. Such a guideline may help clinicians and patients to take the right decision regarding sleeping with or without dentures to improve OHRQoL.

2.2 STUDY OBJECTIVE AND HYPOTHESES

1- The objective of this Master's research project was to investigate the OHRQoL and HRQoL of elderly people suffering from OSA in relation to the nocturnal wearing of complete dentures.

2- The hypothesis

The hypothesis was that the nocturnal wear of dentures improve health and oral health-related quality of life among edentulous patients who are diagnosed with OSA.

The null hypothesis was that there is no difference in the OHRQoL and HRQoL of patients who wear or who do not wear their dentures during sleeping at night.

2.3 METHODOLOGY

2.3.1 Study design

This study was designed as part of a randomized, controlled crossover study (RCT) entitled "The effect of nocturnal wear of complete dentures on sleep and oral health-related quality of life". The protocol of this study and detailed methodology have been previously published (69). The trial design is shown in Figure 2.1.

The major advantage of using the RCT crossover design in this study is to provide strong evidence on the impact of the intervention (sleeping with or sleeping without the dentures) and the outcomes (OHRQoL and HRQoL) with a smaller sample size since each participant serves as his/her own control. Furthermore, the crossover design is a repeated measurement design which allows investigation of the effect of the sequence and the period on the intervention (257).

This Master's research project only focuses on the impact of nocturnal wear of the prosthesis on OHRQoL and quality of life and the descriptions of methodology and results included here are limited to the scope of the Master's project.

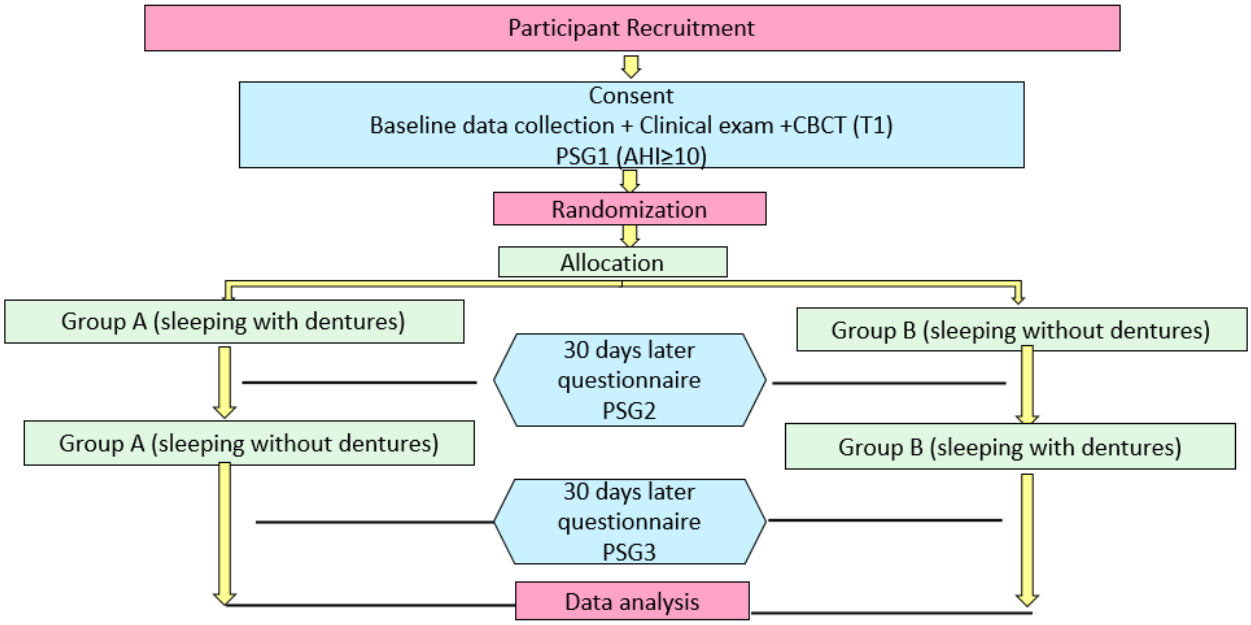


Figure 2.1 Trial design

2.3.2 Study participant recruitment and eligibility criteria

Participants in the randomized controlled trial study (69) were 70 edentulous participants (men and women), aged 65 years or over, living in the metropolitan area of Montreal who have been diagnosed with moderate to severe OSA. From a total of 70 edentulous apneic elderly who were assigned and completed the procedure study, results of only 63 patients were available at the time of data analysis for this Master's project.

Participants were recruited from the former patients of the prosthodontic clinic, the Dental Clinic of the University of Montreal, as well as from those who called following advertisements in neighborhood newspapers and magazines for the elderly. Potential participants were evaluated for the preliminary eligibility and provided with complete and detailed information about the study. As shown in the inclusion criteria (see Table 2.1), potential participants were invited for a first visit to the Oral Health and Oral Rehabilitation Research unit of the Université de Montréal. During this visit, the student met the potential participant, explained to him or her the purpose and the procedures of the study. The consent form was then

signed by the participant and baseline data were collected. During the same week of recruitment, a technician made a baseline overnight sleep recording (PSG1) at the patient's residence via a portable device (polysomnography). If the AHI of the first sleep recording was greater than or equal to 10 (AHI ≥10), then the participant was deemed eligible to enroll in the trial study.

The preliminary inclusion and exclusion criteria are represented in Table 2.1 and Table 2.2.

Table 2.1 Study inclusion criteria

Inclusion criteria:
1) Be 65 years old or older.
2) Have worn full dentures during the last year.
3) Have removed the prostheses at the night, during the last year.
4) Have an apnea-hypopnea index (AHI) greater than or equal to 10.
5) Could well understand English or French (oral and written).
6) Be able to understand and answer the questionnaires used in the study.
7) Agree to adhere to the procedure to be followed throughout the experiment.
8) Do not consume alcohol nor work until a late hour the night of polysomnography.

Table 2.2 Study exclusion criteria

Exclusion criteria:
1) Have severe cardiac neurological, psychological or psychiatric conditions, respiratory illness, acute airway infection or any other health problem that compromises sleep.
2) Have a score of 24 or less on the Mini-Mental State assessment.
3) Regularly consume more than two alcoholic beverages/day for women and three for men.
4) Take medication or any illicit drug that will affect the quality of sleep or the activity of the respiratory muscles (e.g. hypnotics, psychostimulants, anticonvulsants or antipsychotics).
5) Follow a continuous positive airway pressure or other nocturnal oxygen therapy.
6) Have sleepiness considered dangerous and requiring emergency treatment.
7) Consider that this study would be detrimental to their privacy.

2.3.3 Randomization and study intervention

Participants who met the eligibility criteria were randomly allocated by using numbered, sealed, and opaque envelopes containing the intervention sequence. This envelope was mailed to the participants. When the randomization envelope was received, the participant contacted the research assistant to inform her of the sequence and the date of starting the intervention. The intervention was sleeping with or without dentures, alternately, for two sessions of 30 days. At the end of the first and second periods, follow-up data were also collected at the patient's residence.

2.3.4 Data collection

Data collection was conducted at the Oral Health and Rehabilitation Research Unit at the Université de Montréal and at the patients' residence. The sociodemographic characteristic data was collected at the baseline. The data for OHRQoL outcomes was collecting during three visits: at baseline (T_0), one month (T_1) and two months (T_2) after the intervention by means of self-administered questionnaires OHIP-20 and SF-36. Due to the nature of the intervention in this study, it was impossible to blind the participants to the intervention allocation. However the person who collected and entered data was blind to the intervention sequence.

2.3.5 Study outcomes and measures

The primary outcomes for this Master's research project were the OHRQoL and HRQoL To assess OHRQoL, the Oral Health Impact Profile (OHIP-20) questionnaire was used (Annex I). This questionnaire contains 20 items and measures 7 domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicaps. OHIP-20 subscales and item descriptions are shown in Table 2.3. The items were rated on six-point Likert scales ("never"=1, "rarely"=2, "occasionally"=3, "often"=4, "very often"=5 or "all of the time"=6). The score for each subscale as well as the overall OHIP was calculated for every participant after each of the two interventions. The total OHIP score was

calculated by adding up the ratings of all questionnaire items. The overall scores range between 20 and 120 points, with lower scores indicating a better OHRQoL (65, 68).

The HRQoL data were collected through the Short Form (SF-36) questionnaire(51) (Annex II). This generic questionnaire contains 36 items, of which 35 questions assess the 8 HRQoL dimensions: physical functioning, role limitations due to physical health problems, role limitations due to personal or emotional problems, energy, emotional well-being, social functioning, pain, general health; one item investigates health changes over the last year. The HRQoL questionnaire is based on two types of rating scale: 28 items use the ordinal scale and follow the Likert-point format while 7 items use a bilinear scale, answering yes or no, and recorded 1 or 2, respectively (See Table 2.4). In this study, scale scoring was performed by a computer using online calculation software (258). The scaled scores (0-100) are the weighted sums of the questions. The higher score for each dimension indicated a better health status. For example, the higher physical functioning score indicates better functioning and the higher scores for pain subscales indicate no pain (51).

Other analyzed variables included the sociodemographic status collected by the use of a self-administered questionnaire. The BMI was assessed at the research unit and calculated as weight (kg) divided by height squared (m2). The baseline OSA severity was measured by the use of polysomnography at the patient's residence as detailed in the published protocol (69).

Table 2.3 OHIP-20 statement (65, 68)

OHIP-20 subscale	Number of items	Item description	Item code
Functional limitation	3	Difficulty chewing	Q1
		Food catching	Q2
		Ill-fitting dentures	Q3
Physical pain	4	Painful aching	Q4
		Uncomfortable to eat	Q5
		Sores spots in mouth	Q6
		Uncomfortable dentures	Q7
Psychologic discomfort	2	Worried	Q8
		Self-conscious due to oral problem	Q9
Physical disability	4	Avoid eating some foods	Q10
		Unsatisfied with diet	Q11
		Unable to eat	Q12
		Interrupt meals	Q13
Psychologic disability	2	Been Upset	Q14
		Been embarrassed	Q15
Social disability	3	Avoid going out	Q16
		Less tolerant of spouse or family	Q17
		Irritable with others	Q18
Handicap	2	Unable to enjoy people's company	Q19
		Life unsatisfying	Q20

Table 2.4 SF-36 concept (51)

Sf-36 scale	Number of items	Item description	Item code	Scales type
Physical functioning	10	Vigorous and moderate physical activities (walking, running, climbing)	Q3	3-point Likert scale
Role-Physical	4	Difficulty performing the work /need more time	Q4	Binary (yes/No)
Role Emotional	3	Less accomplish and careful	Q5	Binary (yes/No)
Energy (vitality)	4	Have energy/tired	Q9a+Q9e+Q9g+Q9i	6-point Likert
Emotional well-being	5	Feeling nervous/calm	Q9b+Q9c+Q9d+Q9f+Q9h	6-point Likert
Social Functioning	2	Social gathering	Q6+Q10	5-pointsLikert 5
Bodily pain	2	Pain interfere daily work	Q7+Q8	5-point Likert scale
General health	5	Feel sick/healthy	Q1+Q11	5-point Likert scales

Item 2 investigate health changes over the last year and it is not used in HRQoL score

2.3.6 Statistical Analysis

Data were analyzed using descriptive and multivariable statistical tests using the Statistical Package for the Social Sciences (SPSS), version 25 (SPSS Inc., Chicago, IL, USA) and SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Descriptive statistical tests were used to obtain frequency counts, percentages, and means as well as to test for normality. A two-tailed value of $p \leq 0.05$ was selected to represent statistical significance.

A mixed-effect model for repeated measures was used to analyze the impact of wearing denture on OHRQoL and HRQoL taking into account:1) The intervention with: Intervention 1= sleeping with dentures, and Intervention 2=sleeping without dentures. 2) The randomization sequence with: Sequence 1= sleeping with prostheses during the 1st month and without during the 2nd month, and Sequence 2 = sleeping without prostheses in the 1st month and within the 2nd month. 3) The period of measurement with: Period 1= T1 (1 month after allocation of the randomization) and Period 2= T2 (2 months after allocation of the randomization).

2.3.7 Ethical Considerations

This study was approved by the Research Ethics Board of Health of the Université de Montréal (Project 13-076-CERES-D). The trial protocol has been registered in the U.S. Clinical Trial Registry "NCT01868295". All participants gave written informed consent prior to enrolment. All data collected for the study were strictly confidential. Prior to data entry, all data forms were coded according to a personal identification number (PIN). Data records were stored in locked data storage areas.

2.4 STUDY RELEVANCE

The results of this study will provide clinicians scientific evidence on preventive approaches that will contribute to the improvement of the quality of life in apneic edentate individuals wearing complete dentures.

2.5 ROLE OF THE STUDENT

The student participated in data collection and data entry. With the help of statisticians, the student contributed to data analyses and interpretation of the data.

CHAPTER 3: RESULTS

3.1 SOCIODEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS:

At the time of data analysis for this master project, the data of only 63 eligible participants (n=63) who completed the follow-up and the assessment in this RCT crossover study was available. The average age of the participants was ≈74 years old, and 57% of them were women. Only 30% of these study participants were married, while the majority was either widow, divorced, separated or single. Still, 51% of them were living either with family or other adults. Ninety-two percent of all participants were retired, and 78% had household incomes less than $40,000 per year. At the baseline, BMI measurement showed that 39% of the enrolled patients in this study were classified as obese (BMI ≥ 30). The baseline PSG reports showed that 71% of the participants had AHI scores equal or greater than 15 events/h with an initial mean AHI of 26.8 ± 15.2. When comparing the two randomized groups to either sequence 1 (wear-not wear) or sequence 2 (not wear-wear), the chi-squared test did not show any significant difference with regard to sociodemographic characteristics, nor to the BMI and AHI initial scores. This confirms that the two randomized groups are accurately balanced. The sociodemographic characteristics of the participants are shown in Table 3.1.

Table 3.1 Socio-demographic characteristics of the participants at the baseline

Sociodemographic Characteristics				
Variable	**Overall (N=63)**	**Sequence Wear/not wear (N=32)**	**Sequence Not wear/wear (N=31)**	***p* value**
Age (mean ± SD)	74.43 ± 6.59	74.69 ± 7.09	74.16 ± 6.14	0.75
	N (%)	**N (%)**	**N (%)**	
Gender				
Male	27 (43%)	12 (38%)	15 (48%)	0.45
Marital status				
Married	19 (30%)	7 (23 %)	12 (39%)	
Single	9 (14%)	4 (13%)	5 (16%)	0.53
Divorced/Separated/widow	29 (46%)	17 (57%)	12 (39%)	
Other	6 (10%)	2 (7%)	2 (7%)	
Life-style				
With family or other adults	32 (51%)	14 (44%)	18 (58 %)	0.49
Alone	30 (48%)	18 (56%)	12 (39 %)	
Other	1 (1%)		1 (3%)	
Education level				
≥ college	29 (45%)	21 (66%)	14 (45 %)	0.13
Familial income				
≤ 19.999 $	18 (29%)	9 (28%)	9 (30%)	
20 000-39.999 $	31 (49%)	15 (47%)	16 (53%)	0.5
≥ 40 000 $	10 (16%)	5 (16%)	5 (17%)	
Other	4 (6%)	3 (9%)	0 (0%)	
Current Job				
Retired	58 (92%)	30 (94%)	28 (90%)	0.09
Full/part-time	3 (5%)	0 (0%)	3 (10%)	
Home /unemployed	2 (3%)	2 (6%)	0 (0%)	
Obesity				
BMI ≥30	24 (39%)	15 (48%)	9 (29%)	0.19
AHI Index				
(mean ± SD)	26.80 ± 15.17	28.2 ± 15.19	25.36 ± 15.26	0.46

3.2 ORAL HEALTH-RELATED QUALITY OF LIFE

For OHIP-20, $\log_{10}$ was applied to normalize data distribution in the analysis. The level of statistical significance was set at 5% ($p<0.05$).

The linear mixed model for repeated measures was used to assess the effect of the intervention of sleeping with dentures (W) versus sleeping without (NW), on all OHRQoL outcomes.

The model includes 3 independent variables: 1) intervention (W or NW); 2) sequence (W-NW or NW-W); and 3) period (first month [period1] or second month [period 2] after assignment). The effect of the period allows testing of the interaction between intervention and time on OHRQoL outcomes, while the effect of the sequence allows testing for the carry-over effect.

The effect of intervention was estimated, and results showed that the mean score of total OHIP (±SD) when patients slept with dentures was 39.76 ± 18.94, which is slightly higher than the mean scores when they slept without dentures (37.52 ± 19.43), but the difference was not statistically significant (p=0.08) (Figure 3.1). Considering OHIP-20 subscales, sleeping with dentures was associated with greater mean scores compared to sleeping without dentures for 4 OHIP-20 subscales: functional limitation, physical pain, psychological discomfort, and disability, However, this difference was only statistically significant for psycho-discomfort (p=0,037) and physical disability (p=0,050) (Figure 3.2 and Figure3.3). The effect of the intervention on handicap mean scores was similar for the two groups, however wearing dentures during the night has a weak positive impact on the social disability subscale, with lower means scores reported among patients slept with their dentures however this effect is not significate (p=0,48).

In fact, our results did not show a significant effect of period or sequence on any of the OHIP-20 scores, neither global nor subscales, but the first follow-up visit seems to have a small negative impact on handicap subscales; this difference (p=0.053) was slightly below the significance threshold (Table 3.2).

The OHIP-20 Summary of OHIP-20 (overall and subscales) means scores (±SD) at the baseline and at the two follow-up visits are presented in Table 3.3 and Figure 3.4.

Table 3.2 Effects of Sequence, Period and Intervention on OHIP-20 scores, in linear mixed models

Function limitation				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	0.36	0.552
Period	1	60	0.01	0.926
Intervention	1	60	0.91	0.343

Physical pain				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	0.97	0.329
Period	1	60	0.00	0.979
Intervention	1	60	1.01	0.319

Psycho-discomfort				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	1.92	0.171
Period	1	60	0.91	0.345
Intervention	1	60	4.57	0.037*

Physical disability				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	2.27	0.137
Period	1	60	0.13	0.718
Intervention	1	60	4.00	0.050*

Psycho-disability				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	0.58	0.448
Period	1	60	0.05	0.823
Intervention	1	60	1.15	0.288

Social disability				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	2.42	0.125
Period	1	60	0.12	0.728
Intervention	1	60	0.50	0.483

Handicap				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	1.61	0.209
Period	1	60	3.90	0.053
Intervention	1	60	0.28	0.599

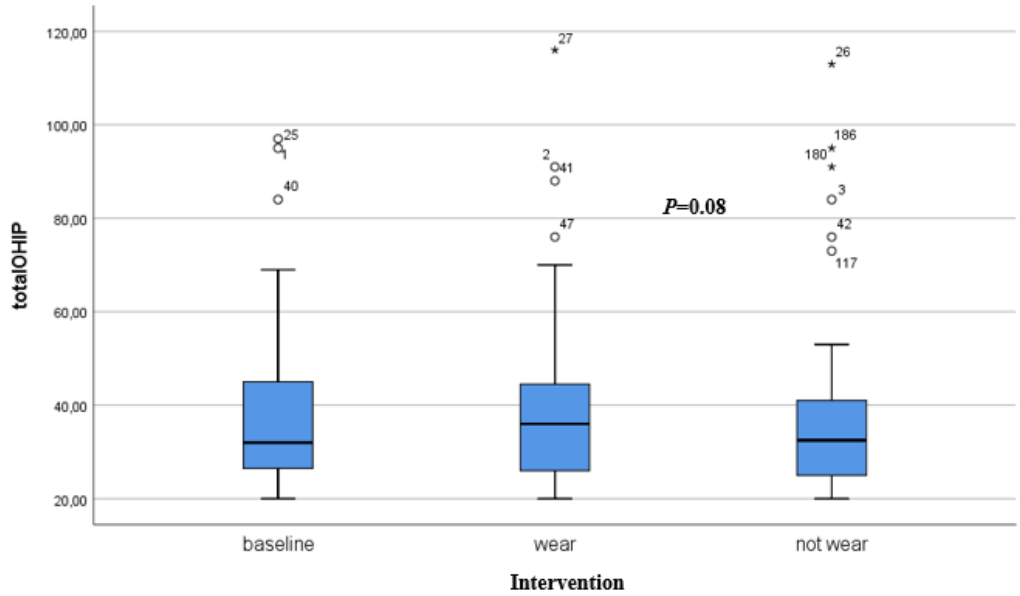
Total OHIP				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61	1.55	0.218
Period	1	60	0.20	0.655
Intervention	1	60	3.27	0.075

DF: Degree of freedom, F: the ratio of two mean squares values, Pr >F: the significance probability
*= P <0.05 (significant), P value interpret the significance level of the intervention assessed by fixed effect model

Table 3.3 Comparison between the mean scores of global and subscales OHIP-20 at the baseline, and the two follow-up

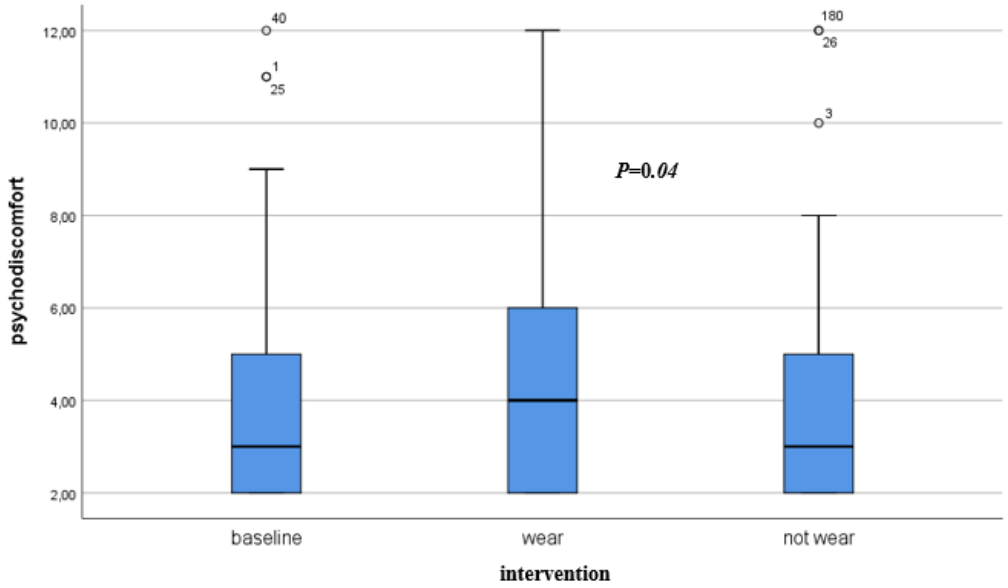
OHIP-20 subscale	Baseline	Intervention		
	Sleep without prostheses n=63	Sleep with prostheses n=63	Sleep without prostheses n=62	Intervention *p* value
Function limitation Mean ± SD	7.62 ± 3.60	7.79 ± 3.74	7.37 ± 3.67	0.34
Physical pain Mean ± SD	8.71 ± 4.16	9.76 ± 4.71	9.16 ± 4.51	0.32
Psycho-discomfort Mean ± SD	4.06 ± 2.58	4.33 ± 2.60	3.84 ± 2.40	0.04*
Physical disability Mean ± SD	6.84 ± 3.82	7.33 ± 4.34	6.66 ± 4.25	0.05*
Psycho-disability Mean ± SD	3.73 ± 2.04	3.93 ± 2.28	3.66 ± 2.13	0.29
Social disability Mean ± SD	3.68 ± 1.70	3.81 ± 2.04	4.02 ± 2.60	0.48
Handicap Mean ± SD	2.84 ± 1.64	2.81 ± 1.72	2.81 ± 1.84	0.60
Total OHIP Mean ± SD	37.49 ± 17.53	39.76 ± 18.94	37.52 ± 19.43	0.08

*= P <0.05 (significant), P value interpret the significance level of the intervention assessed by fixed effect model



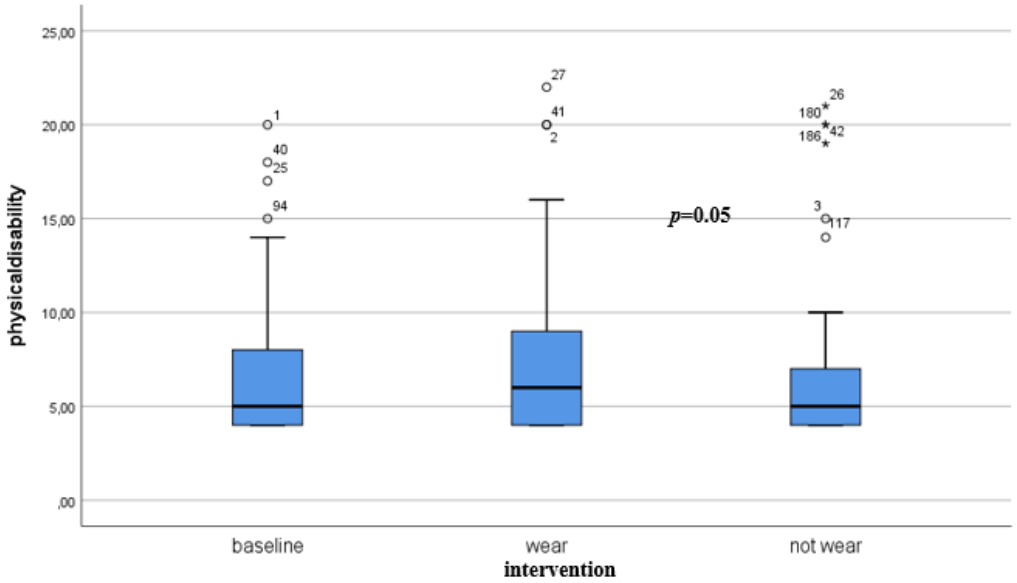
p: the significant effect of the intervention (wear and not wear) assessed in the fixed effect model analysis
Error bar 95% CI

Figure 3.1 Box plots of changes in overall OHIP-20 scores at the baseline and the two follow-up visits



p: the significant effect of the intervention (wear and not wear) assessed in the fixed effect model analysis
Error bar 95% CI

Figure 3.2 Box plots of changes in OHIP psycho-discomfort dimension scores at the baseline and the two follow-up visits



p: the significant effect of the intervention (wear and not wear) assessed in the fixed effect model analysis
Error bar 95% CI

Figure 3.3 Box plots of changes in OHIP physical disability dimension scores at the baseline and the two follow-up visits

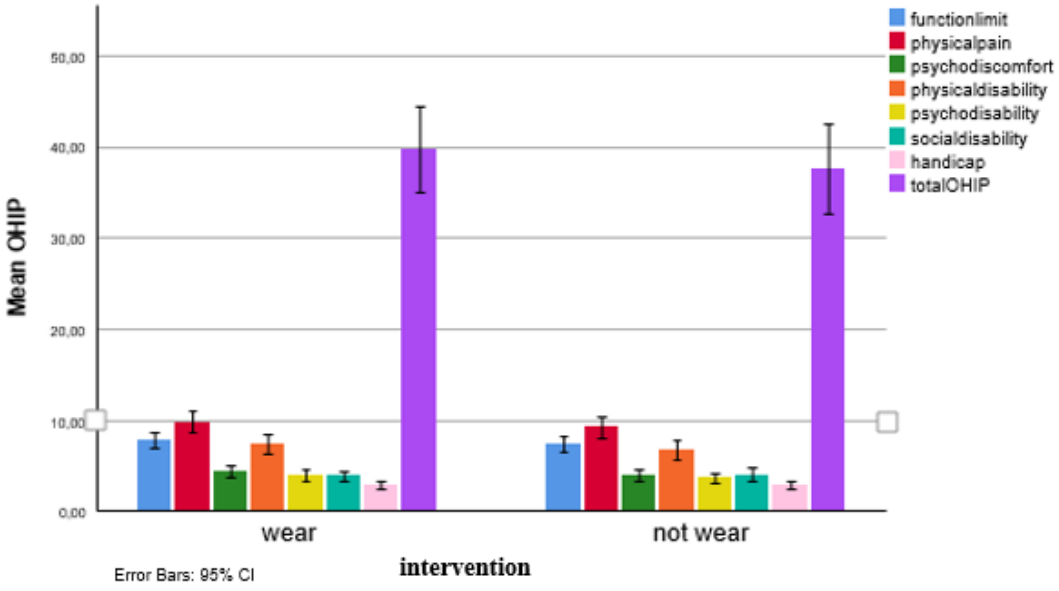


Figure 3.4 Box plots showing changes in all dimensions of OHRQoL at the two follow-up visits

3.3 HEALTH-RELATED QUALITY OF LIFE

In SF-36 analysis, collected data was not in a normal distribution, thus variables were put in ranks, and we used a mixed model for repeated measures (Brunner Langer Method).

Similar to OHIP-20 data analysis, the linear mixed model for repeated measures including intervention, sequence and period, was used to assess the effect of the intervention of sleeping with dentures (W) versus sleeping without (NW) on all SF-36 subscales: physical function, role-physical, role-emotional, energy, emotional well-being, social function, pain, general health and health change (Table 3.4).

The intervention effects assessed by the mixed effect model showed that the means scores (±SD) for all SF-36 components were higher at the baseline than the comparable subscales in both intervention arms. Therefore, the mean scores (±SD) for each comparable SF-36 subscale at the two follow-up visits showed that sleeping with dentures was associated with higher mean scores for all SF-36 subscales, but the statistically significant difference was reported only on the social function subscales, with mean scores of 77.82 ± 22.23 for (NW) versus 84.13 ± 19.98 for (W); p <0.01 (Figure 3.5).

The mean score for the energy subscale also increased from 68.87 ± 25.88 to 72.18 ± 24.16 among patients who slept with their dentures, but this effect was slightly below the significance threshold (p=0.055) (Figure 3.6). Also, statistical analysis showed changes in the means scores for the emotional well-being subscale from 76.95 ± 19.43 (W) to 75.0 ± 19.62 (NW). However, this change is weak and did not reach the statistical significance (p=0.08). The general health subscale scores were also slightly higher among patients who slept with dentures with a difference of 2.26 ± 2.23 in the mean score, but this difference was near the borderline of significance (p=0.097). The mean and the median scores for all SF-36 subscales are presented in Table 3.5 and Figure 3.6 respectively.

In addition, this model showed that the significant effect of the intervention period (T1, T2) on SF-36 subscale was reported only on the SF-36 physical function subscale (p=0.03), with higher mean scores found among patients who wore the dentures during the first period (T1). Furthermore, the assignment sequence had a significant effect on the mean scores of the three SF-36 dimensions; physical function *(*p=0.03), pain (p=0.02), and health change (p=0.02),

which indicated the possibility of a carry-over effect from the first intervention to the second one (Table 3.4). Thus, a second model was needed to determine the impact of intervention on these three SF-36 subscales, by introducing only the intervention variable and analyzing data from the first follow-up visit only. A comparison was made between the group of n=32 participants who slept with dentures and the group of n=31 participants who slept without dentures during the first period. For the carry-over effect, the level of statistical significance was set at 5% ($p<0.05$).

Analysis of SF-36 subscales to investigate the carry-over effect in the first period**:** As shown in Table 3.6, the analysis concerned only the first period and compared the two groups according to the assigned intervention in this first month (W or NW). The mean scores for physical function, pain, and health change were higher at the baseline compared to one month after intervention in the two groups. In addition, at the baseline the mean scores of pain and physical function had lower values in the group assigned to W intervention compared to the NW group. However, opposite results were found for the baseline health change mean score, which was higher in group W.

The sequence ^{x} intervention effect on physical function and pain subscales showed that participants who slept with dentures had lower mean scores than participants who did not, but the difference was not statistically significant ($p=0.09$ for physical function and $p=0.12$ for pain, respectively) (Table 3.5). However, participants who slept with dentures had significantly higher mean scores on health change scores than participants who slept without dentures (53.13±15.23 for W Vs 45.97±11.36 for NW; $p=0.01$).

Table 3.4 Effects of sequence, period and intervention on SF-36 scores, in linear mixed models

Physical function				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	60	4.88	0.027⋕
Period	1	60.4	4.53	0.033÷
Intervention	1	60.4	1.19	0.274

Role-physical				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	60.8	1.55	0.214
Period	1	60.5	0.00	0.958
Intervention	1	60.5	0.28	0.598

Role-emotional				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	60.6	0.11	0.744
Period	1	60.7	0.23	0.633
Intervention	1	60.7	1.59	0.207

Energy				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61.4	1.49	0.222
Period	1	60.1	0.15	0.696
Intervention	1	60.1	3.69	0.055

Emotional well-being				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61.5	0.37	0.545
Period	1	60.1	0.07	0.797
Intervention	1	60.1	3.10	0.078

Social function				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	60.2	1.56	0.212
Period	1	60.6	0.91	0.340
Intervention	1	60.6	8.39	0.004*

Pain				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61.4	5.80	0.016⋕
Period	1	60.1	0.02	0.899
Intervention	1	60.1	2.60	0.107

General health				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	61.8	0.78	0.377
Period	1	59.8	0.41	0.522
Intervention	1	59.3	2.76	0.097

Health change				
Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Sequence	1	62.5	5.35	0.021⋕
Period	1	59.3	0.32	0.573
Intervention	1	59.3	1.65	0.199

DF: Degree of freedom, F: the ratio of two mean squares values, Pr >F: the significance probability
*= P <0.05 (significant), P value interpret the significance level of the intervention assessed by fixed effect model
÷= P <0.05 Significant effect of the period of follow-up visit on the outcomes assessed by fixed effect model
⋕= P <0.05 Significant effect of the intervention sequence on the outcomes assessed by fixed effect model

Table 3.5 Comparison between the mean scores of subscales Short Form (SF-36) at baseline, and the two follow-up visits

FS-36 subscale	Baseline	Intervention		
	Sleep without prostheses n=63	Sleep with prostheses n=63	Sleep without prostheses n=62	Intervention *p* value
Physical function Mean ± SD	78.89 ± 23.92	73.17 ± 23.08 ÷⏚	69.68 ± 26.59 ÷⏚	0.27
Role-Physical Mean ± SD	88.49 ± 22.82	76.98 ± 34.87	73.79 ± 36.62	0.60
Role-Emotional Mean ± SD	91.54 ± 21.56	88.89 ± 26.10	83.87 ± 31.79	0.21
Energy Mean ± SD	73.17 ± 15.84	68.10 ± 18.01	64.92 ± 20.01	0.06
Emotional well Mean ± SD	80.63 ± 12.65	76.95 ± 19.43	75.0 ± 19.62	0.08
Social function Mean ± SD	85.32 ± 17.03	84.13 ± 19.98	77.82 ± 22.23	< 0.01*
Pain Mean ± SD	76.31 ± 22.55	72.18 ± 24.16⏚	68.87 ± 25.88⏚	0.11
General health Mean ± SD	78.25± 15.24	75.32 ± 17.36	73.06 ± 15.13	< 0.1
Health change Mean ± SD	52.38 ± 15.37	51.19 ± 12.24⏚	49.60 ± 15.35⏚	0.20

*= P <0.05 (significant), P value interpret the significance level of the intervention assessed by fixed effect model

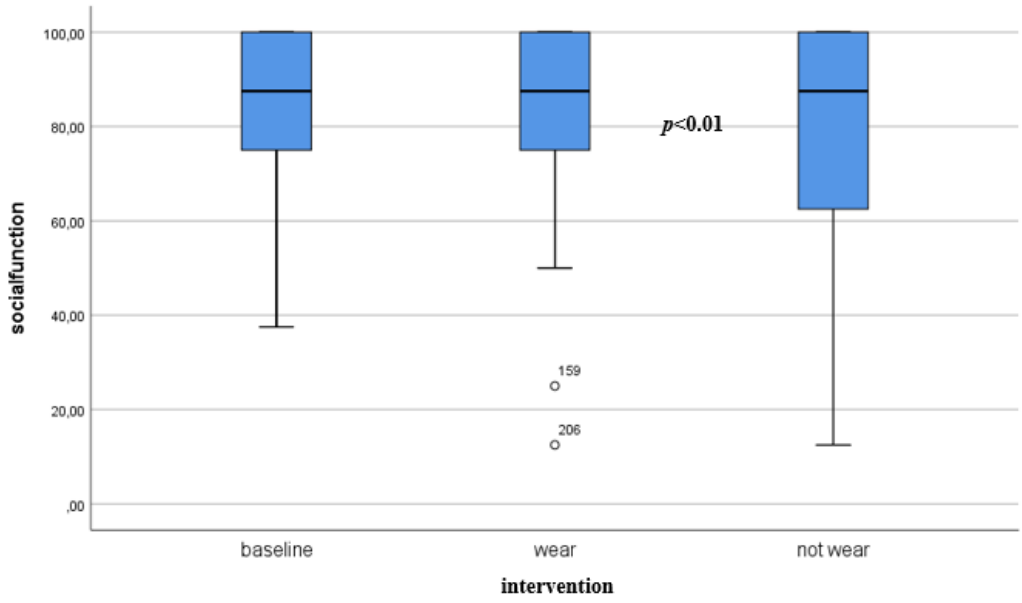
÷= P <0.05 Significant effect of the period of follow-up visit on the outcomes assessed by fixed effect model

⏚= P <0.05 Significant effect of the intervention sequence on the outcomes assessed by fixed effect model

Table 3.6 Effect of the intervention in the first period for physical function, pain, and health change

SF-36 subscale	Intervention sequence wear/ not wear N=32		Intervention sequence not wear/wear N=31		Intervention p value
	Baseline Sleep without prostheses	Sleep with prostheses	Baseline Sleep without prostheses	Sleep without Prosthesis	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Physical function	**68.90 ± 28.21**	**68.13 ± 26.48**	**89.19 ± 11.98**	**80.0 ± 17.03**	**0.09**
Pain	**70.39 ± 24.22**	**65.63 ± 24.90**	**82.42 ± 19.20**	**74.52 ± 26.52**	**0.12**
Health change	**53.91 ± 18.08**	**53.13 ± 15.23**	**50.81 ± 12.05**	**45.97 ± 11.36**	**0.01***

*= P <0.05 Significant effect of the intervention sequence on the outcomes assessed by fixed effect model



p: the significant effect of the intervention (wear and not wear) assessed in the fixed effect model analysis
Error bar 95% CI

Figure 3.5 Box plots of changes in SF-36 social function dimension scores at the baseline and the two follow-up visits

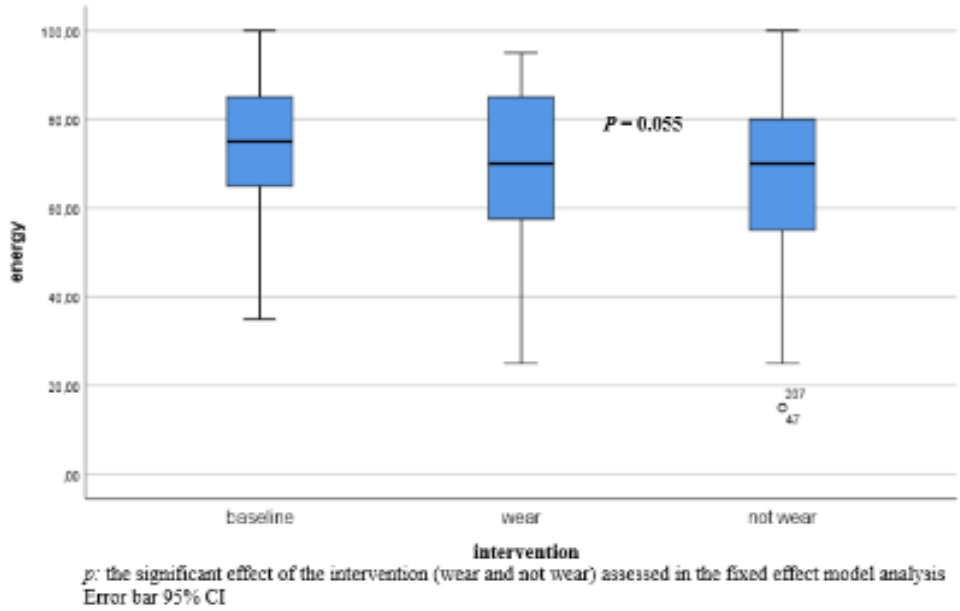


Figure 3.6 Box plots of changes in SF-36 energy dimension scores at the baseline and the two follow-up visits

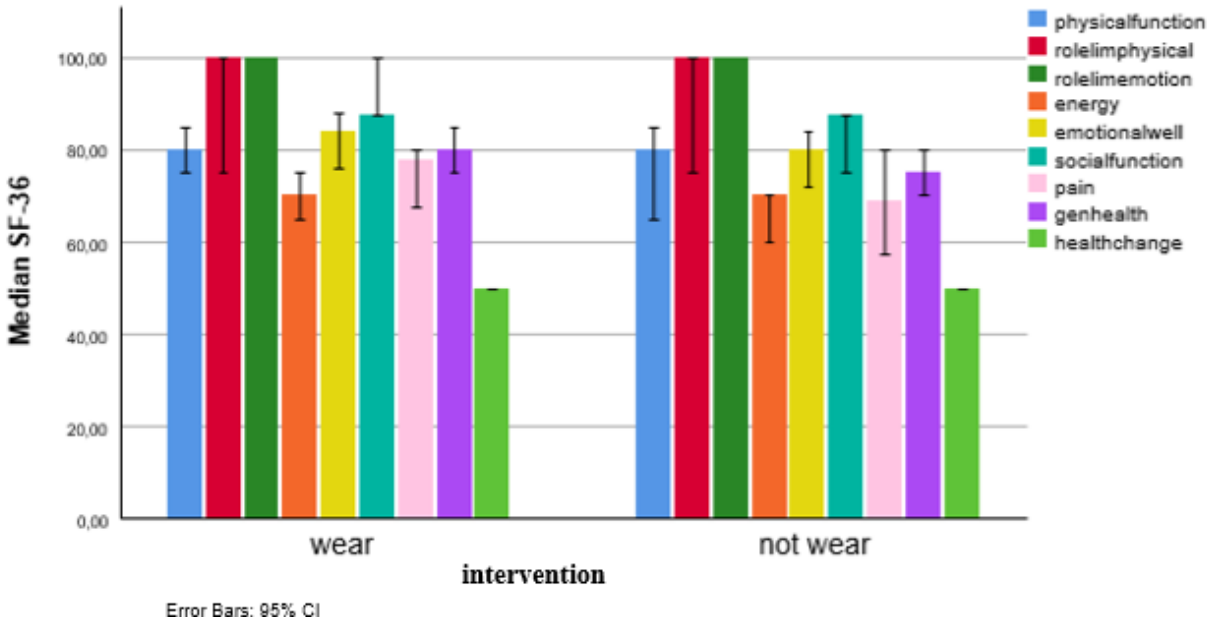


Figure 3.7 Box plots showing changes in all SF-36 scores at two follow-up visits

CHAPTER 4: DISCUSSION

Despite growing interest in dental sleep medicine, to our knowledge, this is the first clinical trial study that provides evidence of patient outcomes with regard to the relationship between sleeping with a dental prosthesis and oral health and health-related quality of life.

The rationale for this investigation is the evidence on the impact of edentulism and wearing dentures on sleep quality, health and oral-related quality of life (103). Previous research findings highlighted the relation between the quality of sleep and HRQoL in the elderly (35, 93, 139). Furthermore, few studies found that AHI index increased among patients who were not sleeping with their dentures (115, 243), whereas other results explained the deterioration in sleep quality among seniors by the effect of geriatric chronic conditions and denture-related problems rather than sleeping with or without the dentures (14, 15, 93, 249, 250). Other studies discussed the relationship between patient satisfaction with their oral conditions and OHRQoL (60, 70, 128, 259). Data from several studies showed that various interventions could have a positive impact on elders' well-being (260, 261).

Quality of life, as was explained in chapter one, refers to patients' comfort, self-confidence, and satisfaction with any intervention (262), consequently, we now present our findings of the impact of the night wearing of dentures on OHRQoL and HRQoL in seniors diagnosed with OSA.

4.1 THE IMPACT OF NOCTURNAL WEARING OF PROSTHESES ON ORAL HEALTH-RELATED QUALITY OF LIFE AMONG THE ELDERLY

The majority of participants in this study reported lower OHRQoL when sleeping with denture with an exception for two dimensions: social disability, which was reduced when patients slept with dentures, and handicap, which remained in the same on average. Additionally, a statistically significant impact was found only on the psycho-discomfort and physical disability aspects of OHRQoL.

In the present study, the global OHRQoL outcome slightly declined among patients when they slept with their dentures. However this change was not influenced by the period (T1

and T2) or by the assignment sequence (W-NW vs NW-W). These results were consistent with the pilot study (163), which found that the higher global OHIP-20 score was associated with sleeping with dentures. However, the association between sleeping with dentures and global OHIP-20 scores in the pilot was not statistically significant (p=0.067). The weak relationship between nocturnal wear of the prostheses and OHRQoL in the pilot study (163) could be due to the smaller sample (n=13) than what we analyzed in this master's study (n=63).

In our study, the change in OHRQoL outcomes does not seem to be strongly and directly related to whether dentures are worn while sleeping or not, but this could be explained by other factors as was presented in the conceptual framework for OHRQoL adapted by Locker in 2004 (44). Based on the Locker concept (44), OHRQoL outcomes are not affected only by oral conditions but could be influenced by other independent variables including personal characteristics, general health status, social and environmental factors (19).

In the present study, the negative impact of sleeping with dentures on psycho-discomfort may be explained by patients being worried about the ejection of their dentures or choking on them while sleeping, especially if subjects wore unstable or ill-fitting dentures (162). Moreover, the decline in the psycho-discomfort dimension could be related to denture-associated halitosis producing by microbial colonization on the denture surfaces (140). Also, some patients may feel worried about the ability to maintain good oral hygiene when they sleep with their dentures, especially patients who had previous oral lesions caused by continuously wearing of dentures and received the recommendation to remove their dentures while sleeping. In addition, all enrolled patients in this study used to sleep without dentures (inclusion criterion), and perhaps they have difficulty coping with a new sleep habit.

Indeed, the decline in the physical disability aspect (avoidance of eating some food, dissatisfaction with diet, inability to eat, meal interruption), which was reported in our study among patients who slept with their dentures, may be explained by the fact that sleeping with dentures could significantly increase the prevalence of some oral lesions such as denture stomatitis and traumatic ulcers, with a higher rate associated with poor oral hygiene and ill-fitted dentures (13, 255). Denture-related lesions may contribute to impairment in oral physical functioning manifested by uncomfortable feelings, and eating and swallowing difficulties (263). In contrast, the social disability outcomes seems slightly better when patients slept with their

dentures, but not at the significant level. That may be due to the discomfort associated with sleeping without dentures especially if the patient are going on a vacation or traveling with others during the intervention period, as expressed by some participants. However, no change was reported in handicap outcomes (inability to enjoy people's company and finding life unsatisfying) whether patients slept with or without their dentures. Our results are comparable to the previously mentioned pilot study (163) where the mean scores in most OHIP-20 subscales slightly increased, except for the physical disability, psychological disability and social disability scores which were higher among the elderly who did not wear their dentures during the night. The variance between the pilot study and our results were probably due to the small sample size in the pilot study (n=13). Moreover, in the present study, the change in OHRQoL outcomes may also be explained by sleep disturbance due to the uncomfortable feeling of wear dentures overnight. That is consistent with a longitudinal cohort study conducted in 2012 by Emami *et al.* (93) on the relationship between OHRQoL and sleep quality and denture status. In that study, they determined that participants who have dentures issues were more likely to suffer from daytime sleepiness and decline in OHRQoL outcomes than their counterparts. This impact was seen in all OHRQoL dimensions, but the significant change was found only on functional limitation (p=0.01) (93). However, we could not completely compare the longitudinal cohort study findings to our study due to the differences in study design and the population between our studies and Emami *et al.* study (93); especially because most participants in that study (84%) were healthy elders and did not sleep with their dentures.

On the other hand, our data analysis did not show significant changes on all OHRQoL domains with regard to whether patients were assigned to sleep with their dentures in the first 30-day follow-up period and without in the second one, or vice versa. Thus, in this trial, we did not detect any carry-over effect of the intervention sequence (sleep with/without dentures) on OHRQoL outcomes.

In the present study, the relationship between OHRQoL outcomes and the nocturnal wear of dentures seems to not be time-dependent, since we did not observe a significant change in any OHIP-20 scores at the two follow-up visits. However, sleeping with dentures seems to have a little impact on handicap domain for the first 30-day follow-up among edentulous elders. In fact, it is difficult to highlight any causal link between the follow-up visit number and handicap

($p>0.05$), but it may be attributed to bias associated with self-reported measures, such as overestimation, recall, and repeated measures bias. For example, patients may habituate or feel tired about answering the same questionnaire three times during the study, which may bias the results, mainly those related to the collected data at T1 and T2 visit, after a night of sleep recording (using PSG). Also, the slight change in the mean scores of the handicap subscale at T2, may be explained by the regression to the mean, since patients at the baseline tended to show that they strongly follow the trial procedure, but in the next evaluation (T2) this mean regressed to the normal average. However, the bias level could also vary according to the subject's expectation, coping style, and interaction with environmental stressors (264-266). Thus, personal adaptation with new intervention procedures and some uncontrolled factors could explain the variance in OHIP handicap scores at the two follow-up visits in our study.

4.2 THE IMPACT OF NOCTURNAL WEARING OF COMPLETE DENTURES ON THE PERCEIVED HEALTH-RELATED QUALITY OF LIFE IN EDENTATE APNEIC ELDERLY

In the present study, we used the Short Form SF-36 to better estimate the degree to which sleep with dentures could affect the quality of life in apneic elderly patients.

The majority of participants in the current study evaluated their HRQoL as relative good, mean scores varied from 75-100% for the eight SF-36 subscales. Health change levels for most participants remained approximately steady compared to the previous year. After the intervention, the SF-36 mean scores for all HRQoL dimensions were found to be higher among patients who slept with their dentures than who did not, which indicated that sleeping with dentures has a positive impact on HRQoL, but the statistically significant impact was found only in social function (interference with social gathering in the last 4 weeks). However, a carry-over effect was found on three dimensions: physical function, pain, and health change. Therefore, we ran another analysis of data collected at the first period (T1). These results showed a significant effect of the intervention on the health change aspect (current health ratings compared to one year previously).

The strong positive impact of sleeping with dentures on social function aspect may be explained by the fact that patients may feel more confident when they wear the prosthesis, allowing them to organize different sorts of social activities such as traveling and camping, without feeling embarrassed by their oral conditions. Moreover, health change in our study was assessed by answering the single question in SF-36, "*Compared to one year ago, how would you rate your health in general now?*" Our data showed a significant improvement in health change rates among the group assigned to sleep with dentures in the first 30-day follow-up dentures compared to the group which did not. In fact, this question was designed to detect a change in the last year, thus this result may be biased because patients were asked to compare their health now with how it was a year previously, not in the last month (the interval time of this study).

Our results found that patients who slept with their dentures felt less tired, less worn-out and reported greater energy levels throughout the daytime compared to the non-wearing intervention period. Furthermore, our results showed a slight improvement in emotional well-being scores (feeling nervous/calm and happy), and physical functioning (vigorous and moderate physical activities) when patients wore their prosthesis during the night. In fact, the difference between groups for physical functioning, energy and emotional well-being in our results were approached or close to the borderline of significance. Similarly, our data analysis noted a slight improvement in general health (feeling sick/healthy), associated with sleeping with dentures, this difference did not reach the conventional significance level.

In this regard, it is worth mentioning that the literature review revealed an association between sleep quality, HRQoL, and OHRQoL (93, 179, 183, 185, 267). Baldwin *et al*. (190) found that severe OSA was associated with impairment in several aspects of HRQoL, including physical functioning, general health, energy and social functioning ($p<0.01$), whereas mild and moderate OSA led to reductions only in the energy aspect. These results may explain the relatively good baseline SF-36 scores among most enrolled patients in our study since they had AHI mean scores higher than 15 events per hour (26.80 ± 15.17). In addition, the effects of sleeping with dentures on HRQoL aspects did not have a significant impact on most HRQoL aspects, including physical functioning, energy, emotional well-being, pain, and health change. This weak relationship found in our study may be due to the smaller sample size that we

analyzed (n=63) than that calculated in the protocol project. Also, it could be explained by the confounding effect of non-health-related factors as it was explained by a systematic review study in 2017, a systematic review performed in 2017 by Huang *et al.* (268) including 67 different studies, showed that personality characteristics, including coping style, social support, emotional distress, may explain 0–45% of the psychosocial aspects and 0–39% of the physical variance of HRQoL which could explain the weak effects of the intervention on the patients in our study as shown in Figure 4.1.

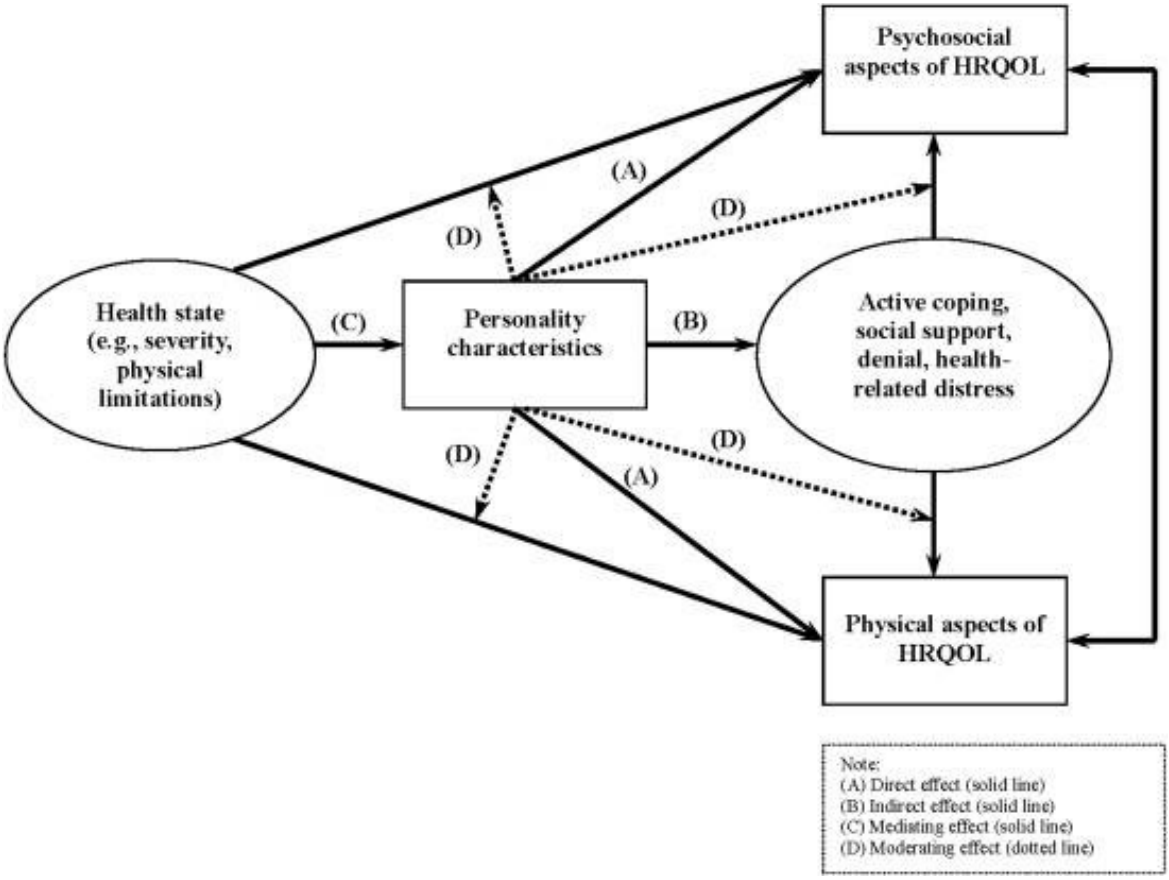


Figure 4.1 The Huang et al.(268) pathway of the impact of the personal characteristics on HRQoL

Several studies showed a decline in HRQoL among patients who had sleep disturbance and concluded that HRQoL outcomes could be a good predictor of adequate night sleep (14, 93,

269, 270), whereas other studies suggested a potential link between wearing dentures at night and different parameters of sleep quality (14, 15, 250). In fact, most of the previous studies explored the clinical impact of sleeping with dentures on OSA rather than estimate patient-centred outcomes, as we did in this study. However, the impact of sleeping with dentures on each aspect of quality of life still has to be clarified.

Actually, the relationship between sleeping with dentures, sleep quality and HRQoL remains controversial (271). Unfortunately, due to the lack of studies performed on the relationship between nocturnal wear of dentures and OHRQoL, we can only compare our results with those of closely related studies, while taking into consideration possible limitations and bias inference due to certain differences. In the present study, the positive impact of the nocturnal wear of dentures on several aspects of HRQoL may partially be corroborated by findings of previous studies with regard to the relationship between wearing dentures during nighttime and sleep quality which consequently had an influence on HRQoL outcomes. In 1999, Bucca *et al*. (243) confirmed that sleeping without dentures leads to collapse on the retropharyngeal space and worsening of OSA (p=0.015). Similar results were revealed in a study conducted in 2011 by Gupta *et al.* (246) which used the cephalometric X-ray to evaluate the impact of wearing dentures on the upper airway. Their findings showed sleeping with complete dentures with suitable VDO could recover an esthetic appearance, help maintain the mandibular in a proper position during sleep and significantly improve the retropharyngeal space (p <0.05). This alteration may enhance elders' self-esteem and improve respiration rates, mainly in patients with OSA who already have a relatively narrow upper airway tract. Results of recent studies carried out on the effect of sleeping with complete dentures on OSA showed a significant increase in AHI events among patients sleeping with dentures; rates may vary depending on the severity of OSA (15, 163, 272). An in-lab sleep study for two consecutive nights done by Chen *et al.* (272) showed increases in AHI rates among all patients whether they had OSA or did not. Almeida *et al.*'s study (15) showed that sleeping with dentures was associated with a significant increase in AHI rates among patients with mild OSA (p <0.005), while they reported no significant change in moderate or severe OSA cases (p=0.2). In contrast, Nguyen *et al*. (163) noted that the significant negative impact was seen only among patient with moderate and severe

OSA when sleeping with dentures p <0.005. However, the small sample size may be considered a limitation of both these studies.

In 2012, Emami *et al.* (93) performed a longitudinal study on the impact of wearing dentures on sleep quality and HRQoL among edentulous elders. Their results did not show a significant difference in sleep quality between sleeping with or without dentures. But they found a positive association between poor sleep quality and low general health scores *(*p<0.05) regardless of whether subjects slept with or without dentures. Our data showed an increase in all SF-36 scores among the denture wearers' group, which may highlight a limit positive effects of sleeping with dentures on HRQoL among apneic patients. Once again, we are not able to define the correlation between sleep quality and the nocturnal wearing of dentures in the current study since our data analysis did not include the impact of sleep quality on HRQoL and OHRQoL. Accordingly, we cannot profoundly compare our results with those of the Emami *et al*. study (93), due to some differences in study design and participants' characteristics which may lead to over- or underestimates of the true association. For example, all the participants in the Emami *et al*. study (93) were selected from a previous trial study in which the participants received new study prosthesis of different types (conventional versus implant retained mandibular dentures). In addition, among all participants in that study, only 8.7% had OSA, and 16% wore their dentures during the night (93). In addition, in the current study, we excluded sleep data from the statistical analysis; this could be one of the hidden confounding factors that may have affected our results.

Furthermore, based on evidence from the literature, we think that data on the impact of wearing dentures on HRQoL could be biased when assessed independently on OHRQoL (273). In Japan, Inoue *et al*. study (273) showed that denture stability had a significant impact on MCS component scores, but when OHRQoL outcomes were assessed and added to data analysis, the impact of denture stability became even stronger with a significant impact seen on both of SF-36 components (PCS and MCS). In fact, we could not use our results to appraise the link between the nocturnal wear of dentures and HRQoL since we did not add dentures stability to our data analysis and we did not use OHRQoL outcomes as a variable in assessing HRQoL.

Overall, in our study, the nocturnal wear of dentures had a positive impact on HRQoL and negative impact on most OHRQoL subscales. The adverse results in our findings may be

explained by geriatric dentistry evidence derived from several studies (10, 93, 273-275). A recent cross-sectional study published in 2019 by Da Mata *et al.* (274) found that the association between HRQoL and OHRQoL could be unpredictable and it was not always significant and may be influenced by numerous confounding factors. Another study showed that oral issues seem to have little impact on HRQoL unless they have an impact on OHRQoL (273). Other studies showed that oral health could explain 28% of the changes in HRQoL (10). Furthermore, another study found that the impact of oral problems on HRQoL was stronger among elders who suffered from more coexistent health issues (275). Thus, an intervention could improve OHRQoL without necessarily having a positive impact on HRQoL (95).

4.3 THE STRENGTHS AND LIMITATIONS OF THE STUDY

4.3.1 Strengths and limitations

To our knowledge, this is the first randomized controlled trial whose aim was to explore patient health related outcomes regarding the wearing of dentures during sleep. Several advantages enhance the validity of this study, the major one being the crossover trial design and homogenous sampling. In this design, patients were randomly assigned to two equivalent groups, receiving sequentially the same intervention in opposite order. Since each patient acts as his/her own matched control, this can reduce the probability of selection bias.

Additionally, our data was collected from a homogenous group with regard to the OSA level (AHI $\geq$ 10) and age ($\geq$ 65 years), minimizing the discrepancy between and within groups. (See Table 3.1)

The study design has the capacity to determine the relationship between the nocturnal wear of dentures and OHRQoL and HRQoL. It is appropriate to examine whether the interaction of confounding factors such as the intervention sequence and administration period may give another explanation to our outcomes.

To ensure a good quality analysis process, the statistical analysis was done by an expert statistician, using the mixed model for repeated measures. This method has some advantages for the trial study, such as the capacity to estimate how the outcome changes over time within each

participant to determine the baseline effects, and is able to deal with "missing at random" data (276).

The main limitation of this master project is that the statistical calculation based on 63 participants instead of 70 participant as per minimum sample size calculated to have enough statistical power. Thus the results should be interpreted with caution.

4.3.2. Internal and external validities

The major biases that might affect the internal validity of the present study are:

Measurement bias: one of the disadvantages of the self-reported questionnaire is recall bias. Recall bias may threaten the validity of our results, especially because the participants were not blinded to their intervention sequence (277).

Habituation with measures: patients may get tired or bored by answering the same questionnaires three times; this may affect the accuracy of the data. For the same reason, some patients did not answer all items, thus the potential for inaccuracy and missing data may affect the reliability of our results.

Since the intervention was administered at the patient's home, we cannot control whether the patient was respecting the protocol with regard to the intervention; this may bias our finding regarding the variables relationship.

Despite the good validity and responsiveness of OHIP-20 in edentulous elders (65) and its good capacity to measure OHRQoL during the daytime, it does not include items to estimate patient outcomes during nighttime. This might hide some undiscovered factors and bias our results.

Our study may contain some degree of bias that may threaten the external validity of our results. Therefore it would be difficult to generalize our findings to a larger population. These biases related to factors including:

Sample recruitment: Patient enrollment was fully voluntary, and the subjects may differ from the general elderly population with regard to their characteristics and lifestyle. For example, all the participants in the present study live in the Montreal metropolitan area; most of

them are independent and are in relatively good health. Thus, it is possible that our sample is over or under-representative of the larger population.

Lack of blinding: Double-blinding is impossible in this type of study since we could not keep patients unaware of the intervention sequence. Therefore their expectation regarding the intervention or their desires to please the researcher could influence their outcomes.

The long-term effect: in this study we assessed the effect within a short interval follow-up (1 month), thus we cannot be sure if sleeping with dentures over a long period of time would have the same impact as shown in our results.

4.4 FURTHER STUDIES

The study of correlations between the nocturnal wear of dentures and OHRQoL is still relatively new in the dentistry research field. Therefore more studies are recommended to clarify this principle and provide a guideline that could help the edentulous elderly with OSA improve their OHRQoL.

Further regression analysis will be needed to explore the potential effect of the intermediate or confounding variables, including anatomical and morphological features of both the oral and the upper airway, denture status, and sleep quality in order to better understand the cause-effect correlation between nocturnal wearing of dentures and OHRQoL in edentulous elders.

Further research with a mixed method design could help investigate other dimensions that have not been covered with existing quantitative instruments. For example, descriptive qualitative study could be useful to explore the patients' experience with regard to wearing or not wearing dentures during the nighttime, and how this experience may impact their OHRQoL.

CHAPTER 5: CONCLUSION

Conclusion:

This study was performed as part of a major study, “The effect of nocturnal wear of complete dentures on sleep and oral health-related quality of life”(69). The results of this Master’s research should be considered as preliminary since the total data analysis has not completed yet.

The preliminary study results suggest that:

Nocturnal wear of dentures has a negative impact on OHRQoL (overall and for most aspects). However, the negative significant impact of sleeping with dentures was detected only on psycho-discomfort and physical disability.

In general, sleeping with or without dentures did not make a difference in HRQoL outcomes, but most patients reported an improvement in social functioning and better health change in the period when sleeping with their dentures.

Further studies will be essential to provide a better understanding of seniors’ need to enjoy a healthy life and to establish a guideline that could help clinicians and patients make the treatment decision that would help improve the OHRQoL of edentulous elders.

In addition, in the present study, we were not able to provide strong evidence regarding a positive correlation between sleeping with dentures and OHRQoL. Accordingly, we recommend that all denture wearers follow the American College of Prosthodontists guidelines (161)which recommend removing prostheses during the night, brushing and rinsing them adequately to maintain good oral health to prevent development of denture-related chronic diseases such as prosthetic stomatitis, ulcers, and bone resorption.

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Annexes

Annex I: The Oral Health Impact Profile (OHIP-20) Questionnaire

OHIP-20E Questionnaire Visit # V1

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	Some of the time	Occasionall	Rarely	Never
1 Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
2 Have you had food catching in your teeth or dentures?	O1	O2	O3	O4	O5	O6
3 Have you felt that your dentures have not been fitting properly?	O1	O2	O3	O4	O5	O6
4 Have you had painful aching in your mouth?	O1	O2	O3	O4	O5	O6
5 Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
6 Have you had sore spots in your mouth?	O1	O2	O3	O4	O5	O6
7 Have you had uncomfortable dentures?	O1	O2	O3	O4	O5	O6
8 Have you been worried by dental problems?	O1	O2	O3	O4	O5	O6
9 Have you been self-conscious because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
10 Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
11 Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
12 Have you been unable to eat with your dentures because of problems with	O1	O2	O3	O4	O5	O6
13 Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
14 Have you been upset because of problems with your teeth, mouth or	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	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

Annex II The Short Form SF-36

I

SF-36 HEALTH SURVEY

Date :

				/			/		
a	a			m	m		j	j	

Identification Code :

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is? (Choose only one answer)

Excellent	Very good	Good	Fair	Poor
○₁	○₂	○₃	○₄	○₅

2. Compared to one year, how would you rate your health in general now? (Choose only one answer)

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than a year ago	Much worse now than one year ago
○₁	○₂	○₃	○₄	○₅

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Only choose one number for each question)

ACTIVITIES:	Yes, limited A lot	Yes, limited A little	No, not limited At all
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports.	○ 1	○ 2	○ 3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.	○ 1	○ 2	○ 3
c. Lifting or carrying groceries.	○ 1	○ 2	○ 3
ACTIVITIES:	**Yes, limited A lot**	**Yes, limited A little**	**No, not limited At all**
d. Climbing **several** flights of stairs	○ 1	○ 2	○ 3
e. Climb **one** flight of stairs	○ 1	○ 2	○ 3
f. Bending, kneeling or stooping	○ 1	○ 2	○ 3
g. Walking **more than a kilometre**	○ 1	○ 2	○ 3

h. Walking **several blocks**	○ 1	○ 2	○ 3
i. Walk **one block**	○ 1	○ 2	○ 3
j. Bathing or dressing yourself	○ 1	○ 2	○ 3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Only choose one number for each question)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities?	○ 1	○ 2
b. **Accomplished less** than you would like?	○ 1	○ 2
c. Were limited in the **kind** of work or other activities	○ 1	○ 2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Choose only one response).

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities	O 1	O 2
b. **Accomplished less** than you would like	O 1	O 2
c. Didn't do work or other activities as **carefully** as usual	O 1	O 2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups? (Choose only one response).

Not at all	Slightly	Moderately	Quite a bit	Extremely
O_1	O_2	O_3	O_4	O_5

7. How much bodily pain have you had during the past 4 weeks? (Choose only one response).

None	Very mild	Mild	Moderate	Severe	Very severe
O_1	O_2	O_3	O_4	O_5	O_6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Choose only one response).

Not at all	A little bit	Moderately	Quite a bit	Extremely
O1	O2	O3	O4	O5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks:

(Choose only one response).)

	All the time	Most of the time	A good bit of time	Some of the time	A little of the time	None of the time
a. Do you feel full of pep?	O1	O2	O3	O4	O5	O6
b. Have you been a very nervous person?	O1	O2	O3	O4	O5	O6
c. Have you felt so down in the dumps that nothing could cheer you up?	O1	O2	O3	O4	O5	O6
d. Have you felt calm and peaceful?	O1	O2	O3	O4	O5	O6
e. Did you have a lot of energy?	O1	O2	O3	O4	O5	O6

f. Have you felt downhearted and blue?	O1	O2	O3	O4	O5	O6
g. Did you feel worn out?	O1	O2	O3	O4	O5	O6
h. Have you been a happy person?	O1	O2	O3	O4	O5	O6
i. Did you feel tired?	O1	O2	O3	O4	O5	O6

10. During the past 4 weeks, how much of the time has your physical or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Choose only one response).

All the time	Most of the time	Some of the time	A little of the time	None of the time
O1	O2	O3	O4	O5

11. How TRUE or FALSE is each of the following statements for you? (Choose only one response).

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	O1	O2	O3	O4	O5
b. I am as healthy as anybody I know.	O1	O2	O3	O4	O5
c. I expect my health to get worse.	O1	O2	O3	O4	O5
d. My health is excellent.	O1	O2	O3	O4	O5