Université de Montréal

A randomized follow-up study of the general health and quality of life of an elderly edentulous population wearing either mandibular two-implant overdentures or conventional dentures

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Thèse présentée à la faculté des études supérieures

en vue de l'obtention du grade de

Docteur de Philosophie (Ph.D.)

en Sciences biomédicales

Décembre 2008

Université de Montréal

Faculté des études supérieures

Cette thèse intitulée :

A randomized follow-up study of the general health and quality of life of an elderly edentulous population wearing either mandibular two-implant overdentures or conventional dentures

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RÉSUMÉ

L'augmentation de la population âgée dans la société indique que les systèmes de soins de la santé font face à de nouveaux défis. Les hauts niveaux d'incapacité qui en résultent peuvent être réduits par les nouvelles technologies, la promotion de la santé ainsi que des stratégies de prévention. Les écrits scientifiques récents soulignent la supériorité des prothèses dentaires implanto-portées par rapport aux prothèses conventionnelles en termes de satisfaction et de qualité de la vie des patients. Cependant, il n'est toujours pas clair si ces avantages ont des effets positifs à long terme sur la santé orale et générale ainsi que sur la qualité de vie des populations âgées.

Objectifs, Hypothèses : Notre but était de mesurer l'impact des prothèses mandibulaires retenues par 2 implants sur la qualité de vie associée à la santé bucco-dentaire et générale ainsi que sur la santé orale et la qualité du sommeil des aînés édentés. Nous avons évalué les hypothèses nulles suivantes : il n'y a aucune différence entre les individus portants des prothèses mandibulaires retenues par 2 implants (IODs) et ceux qui portent des prothèses conventionnelles (CDs), par rapport à la qualité de vie reliée à la santé bucco-dentaire et générale, la santé orale et la qualité du sommeil, un an après avoir reçu leurs nouvelles prothèses.

Méthodes : Dans cette étude randomisée contrôlée, 255 aînés ont reçu au hasard IODs ou les CDs, les deux types de prothèses étant opposés à des prothèses maxillaires conventionnelles. La qualité de la vie reliée à la santé bucco-dentaire (OHRQoL) et la santé générale subjective ont été mesurées avec les questionnaires Oral Health Impact Profile (OHIP-20) et Short Form-36 (SF-36) en condition pré-traitement et après un an. La qualité du sommeil et la somnolence diurne ont été mesurées à l'aide du questionnaire Qualité de Sommeil de Pittsburg et de l'Échelle de

Somnolence Epworth. La santé orale a été évaluée par un examen clinique. Les variables indépendantes étaient le sens de cohérence et le type de prosthèse, ainsi que des variables socio-démographiques. En utilisant des analyses statistiques bi et multi-factorielles, des comparaisons à l'intérieur d'un même groupe et entre deux groupes ont été effectuées.

Résultats : Les différences pré et post traitement pour les cotes OHIP étaient significativement plus grandes pour le groupe IOD que le groupe CD ($p<0.05$). Le type de traitement et la cote pré-traitement étaient des facteurs significatifs à OHRQoL ($p < 0.0001$). Dans le groupe CD, il y avait une diminution significative par rapport aux cotes de «Physical Component Scores (PCS)», le fonctionnement physique, le rôle physique et la douleur physique entre les données pré-traitement et un an après le traitement, ce qui indique une diminution au niveau de la santé générale subjective. Dans le groupe IOD, une diminution statistiquement non significative a été remarquée par rapport à toutes les cotes des sous-échelles de SF-36, sauf pour la douleur physique. Le modèle final de régression a démontré qu'après ajustement pour les variables âge, sexe, statut marital et type de traitement, la cote totale finale d'OHIP et les données de bases de PCS prédisaient la cote finale de PCS ($p < 0.0001$). Aucune corrélation significative entre sens de cohérence et OHRQoL n'a été détectée ($r =-0.1$; $p > 0.05$).

Les aînés porteurs des prothèses conventionnelles avaient presque 5 fois plus de chance d'avoir une stomatite prothétique que ceux portant des prothèses mandibulaires hybrides retenues par 2 implants ($p < 0.0001$). Les aînés ayant subjectivement une mauvaise santé générale avaient une qualité de sommeil moins bonne que ceux avec une meilleure santé générale subjective ($p < 0.05$). Les personnes qui avaient une OHRQoL moins bonne étaient presque 4 fois plus

somnolentes pendant le jour que celles avec une meilleure OHRQoL (p=0.003, χ^2; OR =3.8 CI 1.5 to 9.8). L'analyse de régression a montré que la santé générale subjective et OHRQoL prévoient la qualité du sommeil (p=0.022 et p=0.001, respectivement) et la somnolence diurne (p=0.017 et p=0.005, respectivement).

Conclusions:

Les résultats de cette étude suggèrent que, chez les aînés édentés, des prothèses mandibulaires hybrides retenues par deux implants amènent une amélioration significative de la qualité de vie reliée à la santé bucco-dentaire et maintiennent la sensation d'une meilleure santé physique.

Des prothèses hybrides implanto-portées peuvent contribuer à la santé orale en réduisant les traumatismes infligés à la muqueuse orale et en contrôlant la stomatite prothétique. Les aînés édentés dont le niveau de qualité de vie reliée à la santé bucco-dentaire est bas, peuvent aussi avoir des troubles de qualité du sommeil.

Mots- clés :

Essai randomisé contrôlé, prothèse implanto-portée hybride, santé générale, qualité de vie, stomatite prothétique, sommeil, sens de cohérence

ABSTRACT

The global greying of society indicates that health care systems face new challenges. High levels of disability can be reduced through new technologies, health promotion and preventive strategies. Recent literature has underlined the superiority of mandibular implant overdentures over conventional dentures for patient satisfaction and quality of life. However, it is still not clear whether this benefit has any long-term positive effects on oral and general health, as well as on the quality of life of elderly populations.

Objectives, Hypotheses: We aimed to measure the impact of mandibular two-implant overdentures on the general and oral health quality of life, as well as on oral health and sleep quality of edentulous elders. We tested the null hypothesis that there is no difference in the general and oral health quality of life, as well as, on oral health and sleep quality of those wearing mandibular two-implant overdentures (IODs) and those who wear conventional dentures (CDs), one year following prosthesis delivery.

Methods: In this randomized controlled trial, 255 elders randomly received IODs or CDs, both opposed by conventional maxillary dentures. OHRQoL and perceived general health were measured with the Oral Health Impact Profile (OHIP-20) and the Short Form-36 (SF-36) at baseline and after one year. Sleep quality and daytime sleepiness were measured with the Pittsburg Sleep Quality global score and the Epworth Sleepiness Scale. Clinical exams were conducted to evaluate oral health. Independent variables included sense of coherence and prosthesis type, as well as socio-demographic variables. Between and within group comparisons were performed using bivariate and multivariate statistical tests.

Results: Pre/post treatment differences in OHIP scores were significantly greater for the IOD than the CD group ($p<0.05$). Type of treatment and pre-treatment scores were significant contributors to OHRQoL ($p<0.0001$). In the CD group, there was a statistically significant decrease in physical component scores (PCS), physical functioning, role physical and bodily pain from baseline to one year follow up, indicating decreased perceived general health. In the IOD group, no statistically significant decrease was seen in SF-36 subscale scores from baseline to one year, except for bodily pain. The final regression model demonstrated that, after controlling for age, sex, marital status and type of treatment, the OHIP total final and the PCS baseline scores predict PCS final scores ($p<0.0001$). No significant correlation between sense of coherence and OHRQoL was detected ($r= -0.1$; $p> 0.05$).

Elders wearing conventional dentures were almost 5 times more likely to have denture stomatitis than those wearing mandibular two-implant retained overdentures ($p < 0.0001$). Elders with low perceived general health had poorer sleep than those with high perceived general health ($p<0.05$). Those with low oral health related quality of life were almost 4 times sleepier during the day than those with high OHRQoL ($p=0.003$, χ^2; OR =3.8 CI 1.5 to 9.8). Regression analysis showed that perceived general health and OHRQoL predict sleep quality ($p=0.022$ and $p=0.001$, respectively) and daytime sleepiness ($p=0.017$ and $p=0.005$, respectively).

Conclusions:

The results of this study suggest that, in edentulous elders, mandibular two-implant overdentures provide significant improvement in oral health related quality of life and maintain perceived physical health. Implant overdentures may contribute to oral health by reducing oral mucosa trauma and control denture stomatitis. Edentulous

elders whose oral health related quality of life is low may also have poor sleep quality.

Keywords: Randomized clinical trial, implant overdenture, general health, quality of life, denture stomatitis, sleep, sense of coherence

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LIST OF SYMBOLS AND ABBREVIATIONS

AOR	Ajusted Odds Ratio
CD	Conventional Denture
CDs	Conventional Dentures
CI	Confidence Intervals
CIHR	Canadian Institutes of Health Research
DS	Denture Stomatitis
ESS	Epworth Sleepiness Scale
ES	Effect size
GARS-D	Groningen Activity Restriction Scale-Dentistry
IOD	Implant Overdenture
IODs	Implant Overdentures
IPD	Individual Patient Data
IRB	Institutional Review Boards
ITT	Intention To Treat
HSCL	Hopkins Symptom Check List
HRQoL	Health Related Quality of Life
MCS	Mental Component Summary
LASA	Linear Analogue Self-Assessment
NSP	Non-Starch Polysaccharides
OHIP	Oral Health Impact Profile
OHRQol	Oral Health Related Quality of Life

OR	Odds Ratio
OSA	obstructive Sleep Apnea
PCS	Physical Component Summary
PSQI	Pittsburg Sleep Quality Index
QoL	Quality of life
QUOROM	Quality of Reporting of Meta-Analyses
RCT	Randomized controlled trial
REM	Rapid Eye Movement
SD	Standard Deviation
SF-36	Medical Outcomes Short Form 36
SOC	Sense Of Coherence
SOC 13	The Orientation to Life questionnaire with 13 questions
SPSS	Statistical Package for the Social Sciences
VAS	Visual Analogue Scale
WHO	World Health Organization

ACKNOWLEDGMENT

I would like to express my gratitude to Dr. Jocelyne Feine, who started me on this path, supported and guided me all through the years that I have worked on my PhD project; I thank her for believing in my capacity to work independently and successfully on this project.

I am also indebted to Dr. Pierre de Grandmont who made it possible for me to continue my studies in two institutions and also for his pertinent comments and helpful advice.

I am most grateful to Dr Claude Lamarche and Dr. Gilles Lavigne who facilitated the administration part of my doctoral project.

I thank Dr. Jean Barbeau for his close collaboration and support.

Many thanks go to all those involved in this project in one way or another over the past years, in particular: Pierre Rompré for his skillfull collaboration on the statistical part of this study, Jacynthe Séguin for her friendly advice and help, as well as her technical supervision of the microbiological analyses, Dr Shaoxia Pan and Jean François Ross who helped me in data gathering, Nicolas Drolet, Stephanie Wollin and Negar Taghavi for their research assistance.

Finally, my deep love and gratitude go to my husband, Freydoun, and my daughter, Sara, for standing by me through thick and thin in making my dream come true.

This study was funded by CIHR Industry Grant # UCR-36052 with Straumann Canada Limited and by the ITI foundation. I was supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research, which has led to CIHR Clinician Scientist Award.

This thesis is decidated to my loves:

Sara, Freydoun and my parents

CHAPTER 1

Science is built up with facts, as a house is with stones. But a collection of facts is no more a science than a heap of stones is a house.

Jules Henri Poincaré

Science and Hypothesis (1908)

Introduction

Prosthodontics is "*The discipline of dentistry concerned with the consequences of congenital absence or acquired loss of oral tissues on appearance, stomatognatic function, comfort, and local and general health of the patient, and with the methods for, and assessment if more good than harm is done by, inserting artificial devices made from aloplastic materials to change these conditions*"[1]. Thus, prosthodontic research not only focuses on development of new health technologies, but also emphasizes the assessment of a wide range of outcomes in real world settings.

Outcomes are changes, either favourable or unfavourable, in the actual or potential health status of individuals that can be attributed to health care interventions. Edentulous elders are one of a target population in prosthodontics research, as well as in clinical practice. Many of their characteristics such as their general health, their quality of life, their perceived well being, their treatment satisfaction and their self-

esteem appear to be related to their oral health status [2]. Psycho-social discomfort, suboptimal masticatory performance and functional limitation continue to be significant problems for elders wearing and dealing with conventional prostheses [3, 4]. Therefore, it is essential to test and detect any potential increased effectiveness of new interventions in comparison with conventional treatments for this target group. It is also critical to follow up health care outcomes and to assess the cost-effectiveness of these new technologies.

This chapter consists of an introduction with a review of the literature offering background knowledge on edentulism and its impact on oral and general health, quality of life and sleep.

1.1 Edentulism

1.1.1 Definition and Epidemiology

Edentulism is a debilitating and irreversible disease, defined as the absence or complete loss of all natural dentition. In other words, edentulism is the final marker of disease burden for oral health [5].

Although the prevalence of complete tooth loss has declined over the last decade [6-10], edentulism remains a major disorder all around the word (Table 1), and a large number of people still depend on removable dentures for oral function [8, 11]. The prevalence of complete edentulism varies among countries and between geographical regions

within countries [12]. Direct comparison between national samples is difficult because of various confounding variables such as education, urbanisation, economic circumstance, attitudes to dental care and lifestyle factors [13]. In the United States, the number of edentulous individuals is likely to stay stable at 9 million and, according to the most current information from 2005, the prevalence of edentate persons range from 13% to 42% [14-16]. In 2003, 9% of Canadians aged 15 or older, and 30% of individuals aged 65 and older were completely edentate. [12]. The province of Quebec, had the highest rate of edentulism (14%) and the Northwest Territories had the lowest rate (5%) [12]. It is suggested that Quebec's high rate of edentulism is related to less access to fluoridated water and a high rate of smoking [12, 17].

In general, tooth loss is more prevalent among women than men [12, 18]. Studies show that edentulism is closely associated with socio-economic factors and its prevalence is greater in poor populations [12, 19]. In 2003, the ratio of edentulism was 6 times higher in low-income than in higher income Canadian families [12]. The persistence of socio-economic disparities over the last 30 years [5, 6, 12] leads us to believe that edentulism is still a significant problem and that measures must be taken to better address the relationship between economics and oral health [20]. Other factors contributing to the prevalence of complete tooth loss are age, education, access to dental care, dentist/population ratios and insurance coverage [6, 21].

1.1.2 Denture use

In 2003, approximately 9% of Canadian edentate people coped with their edentulous state without wearing denures [12]. Similarly, studies in other countries have also demonstrated a high prevalence of edentulous people wearing no prostheses [18]. Dentures are commonly used by elders. In some countries, one-third to half of the elders wears complete dentures in one or both jaws [22, 23]. According to the "2003 Canadian Community Health Survey", 24% of people aged 15 or older wear dentures [12]. Denture use was most prevalent among women, people in low income households and those with no dental insurance coverage [12]. Recent studies have demonstrated that denture wearing continues to increase due to the increase in the aging population [8, 10]. As the proportion of older people continues to grow worldwide, the percentage of elders will increase by 24% over the next few decades [24]. By 2050, approximately 2 billion people will be aged 60 years and older. This demographic revolution suggests that the demand for treatment of the edentulous jaw will continue, and the complete denture market will get bigger over the first two decades of the 21st century [8].

Table 1. Prevalence of edentulousness in the elderly reported for selected countries

(Source World Health Organization Global Oral Health Data , 2000)

WHO Region/Country	Percentage edentulous	Age group (Years)
African		
Madagascar	25	65-74
The Americas		
Canada	58	65+
USA	26	65-69
Eastern Mediterranean		
Egypt	7	65+
Saudi Arabia	31-46	65+
European		
Austria	15	65-74
Bosnia and Herzegovina	78	65+
Bulgaria	53	65+
Denmark	27	65-74
Finland	41	65+
Germany	25	65-74
Iceland	72	65+
Italy	13	65-74
United Kingdom	46	65+
South-East Asia		
India	19	65-74
Indonesia	24	65+
Thailand	16	65+

1.2 Edentulism, general health and quality of life

1.2.1 Conceptual model

Oral health is an important component of health, especially if health is regarded as an overall-well being within the conceptual definitions of the World Health Organization: "*Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*" [25].

Crude measurements of mortality and morbidity do not show the complete dimension of health. In developed countries, two-thirds of the burden from disease are caused by physical, mental, and social disability [26, 27]. Thus, the impact of chronic diseases, such as edentulism, on general health should be examined by analyzing the major dimensions of health: physical symptoms and functional capacity, social functioning and perception of well being.

According to the literature, the relationship between edentulism and general health appears to be multidimensional and complex, involving many pathways. Some authors have proposed models of oral and general health [28-31]. Within the conceptual model enunciated by Locker [30], edentulism can lead directly to impairment, functional limitation, physical, psychological and social disability and handicap.

To highlight pathways between edentulism and general health, a conceptual model was developed that describes how edentulism and general health may relate to one another (Figure 1).

Further, the literature has been reviewed according to the components of this model.

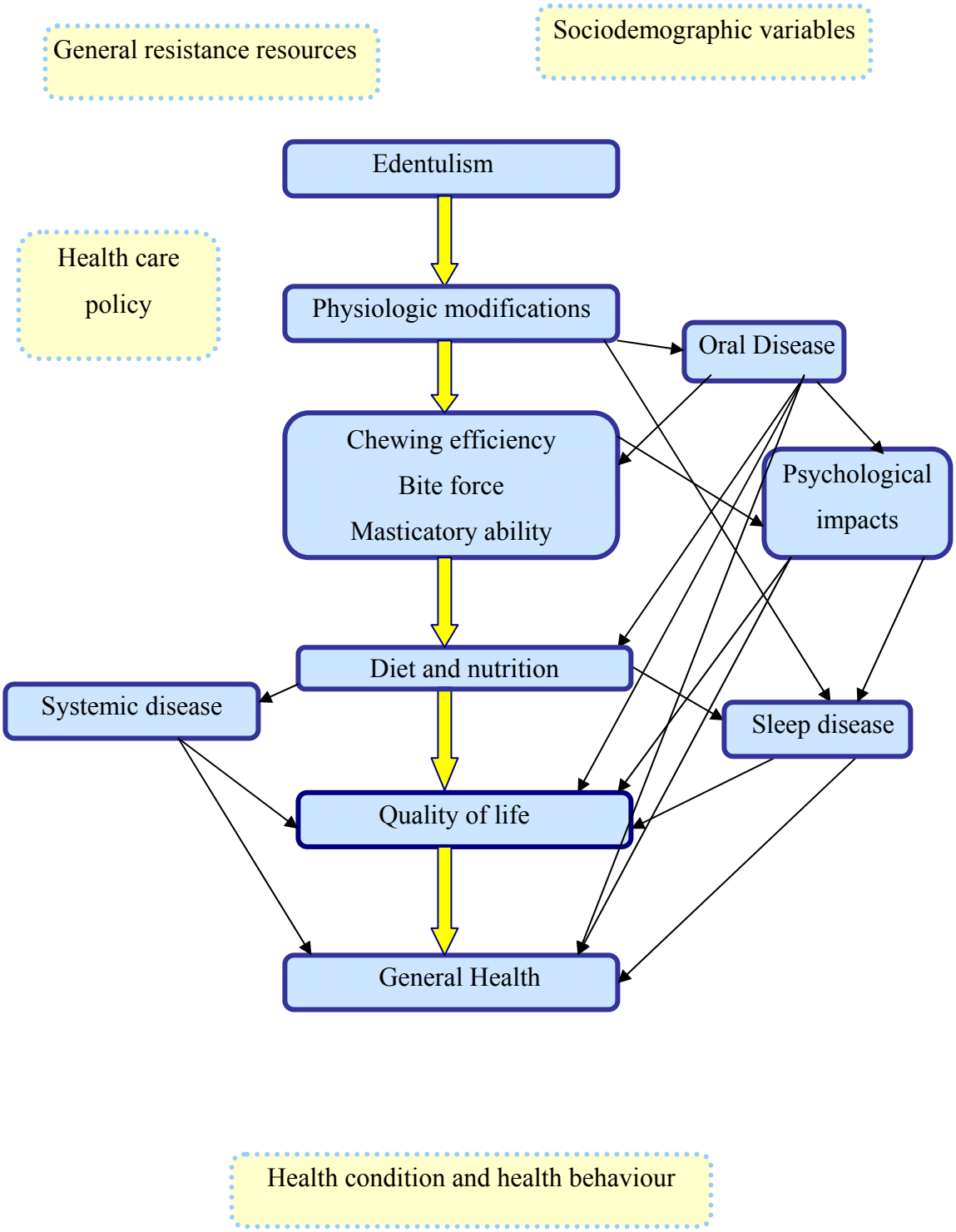

Figure 1. Conceptual model showing pathways for the edentulism-general health relationship

1.2.2 Physiologic modifications associated with edentulism

Bone loss is an ongoing process following tooth loss [32, 33], and it affects the mandible 4 times more than the maxilla [34]. However, there is a significant change in the pattern of mandibular bone loss if patients are treated with mandibular overdentures [35]. Bone loss leads to a reduction in the height of alveolar bone and the size of the denture bearing area. Face height and facial appearance are altered following total tooth loss [33]. The loss of alveolar bone height and width also leads to substantial changes in the soft-tissue profile, such as protrusion of the mandibular lip and chin [36].

There exists an inter-patient variation in these anatomical modifications, but the reasons are still unclear. It is believed that a combination of local and systemic factors may contribute to these changes [37].

1.2.3 Influence of edentulism on masticatory function

The number of teeth has been chosen as a key determinant of oral function and oral health status [38, 39]. Several studies using different methodologies have demonstrated that an important indicator for masticatory efficiency is the number of functional tooth units [40-42]. According to a recent systematic review, tooth numbers below a minimum of 20 teeth, with nine to 10 pairs of contacting units, is associated with impaired masticatory efficiency (performance, capacity) and masticatory ability (an individual's perception of his/her ability to chew) [38]. Edentulism can substantially influence the ability and desire to bite, to chew and to

swallow [7, 18, 43]. Edentulism decreases the swallowing threshold performance, increases the number of chews and the time needed for chewing strokes [44]. Although some evidence suggests that reduced oral function in elders is related to muscle atrophy in this age group, aging alone has little impact on masticatory performance [45]. Most studies agree that denture wearers have only about one-fifth to one-fourth the bite strength and masticatory force of dentate individuals [33, 46-48]. Furthermore, complete denture wearers require 7 times more chewing strokes than those with natural dentitions to be able to cut the food into half of its original size [49]. This may partly clarify why individuals wearing complete dentures have difficulty chewing hard foods. According to Agerberg and Carlsson [50], individuals who were edentulous in one jaw reported decreased chewing ability to the same extent as those who were edentulous in both jaws. Denture wearers compensate for this disability by modifying their food choices [7, 11, 43, 48, 51]. Research has consistently demonstrated that tooth loss and dental status has a negative impact on diet and food selection [33, 47, 52].

1.2.4 Influence of edentulism on diet and nutrition

Adequate dietary intake (regular course of eating and drinking adopted by a person) and nutritional status (state of the body in relation to the consumption and utilization of nutrients) are essential components of health, and dietary practices are one of many health behaviour indicators [53-57]. Acute and chronic diseases, alterations in the gastrointestinal tract, functional disabilities and chewing problems may affect food intake and nutritional status. Physiological, psychological and social factors as well as lowered socioeconomic status may also influence the nutrition [11, 58].

Several longitudinal, prospective and cross-sectional studies have supported the association between tooth loss, diet and nutrition. Impaired dentition imposes dietary restriction, affects food taste, food selection, food preparation and food eating patterns [41, 59-61]. Results of a study by Locker [62] indicated that 39% of edentulous elders were prevented from eating foods they would like to eat, 29% reported a decline in their enjoyment of food, and 14 percent avoided eating with others. Suboptimal diets may prevent edentulous individuals from meeting recommended dietary allowances and lead to compromise nutritional states [7, 11, 42, 63, 64]. Studies have demonstrated that diet in edentulous subjects consists of food that is low in fiber and high in saturated fat, with a significant lack of intake of high-fiber foods such as breads, fruits, vegetables and non-starch polysaccharides (NSP)[11, 42, 65-68]. NSP intakes of less than 10 g/d, and fruit and vegetable intakes of less than 160 g/d, have been reported in edentulous people [10]. Elders wearing dentures have poorer nutritional status than dentate elders, even when socio-demographic factors have been taken into account [68]. Joshipura et al. [69] collected dietary intake data from 49,501 male health professionals and demonstrated that, compared to dentate individuals, edentulous respondants consumed fewer vegetables, less fiber and less carotene intake, while at the same time, consumption of more cholesterol and saturated fats. These differences were independent of socio-demographic and health behaviour characteristics. Lowe et al. [70] demonstrated that total tooth loss was associated with low citrus fruit consumption, low plasma vitamin C levels and increased amount of inflammatory reactants such as plasma C-reactive protein. They also demonstrated increased level of plasma interleukin-6, fibrinogen, and factor VIII levels in women. These factors increase the risk of coronary heart diseases and stroke.

Despite these evidences, some findings contradict the association between dentition and nutrition [61, 71-73]. In a cross-sectional study, Shinkai et al. [61] investigated the influence of dentition status on overall diet quality. The author concluded that, although individuals with better dentition status had better masticatory performance and bite force, no association was found between dentition status and quality of diet. However, in the same study, they found an association between masticatory variables and intakes of specific dietary components such as vitamin C and fiber. There also exist some contradicting results regarding the influence of socio-demographic variables on the dentition-nutrition relationship [59, 71-73]. Findings of Nowjack-Raymer et al. [59] demonstrated that the association between dentition and nutrition was independent of the effects of age, sex, race-ethnicity and socio-economic factors. Lee et al. [74] demonstrated racial-ethnic differences in dietary intake patterns, showing that food intake of black edentulous elders was similar to those with teeth. However, caucasian edentate elders demonstrated different dietary food patterns than their dentate counterparts. This ethnic difference could be explained by fundamental differences in socio-economic characteristics of racial groups. Blacks consumed more fat, fewer vegetables and less fiber than did the caucasiens, irrespective of dental condition [75].

Although diet has been shown to be poorer in edentulous populations, there is still a lack of information about the association between tooth loss and specific changes in nutrient intake.

1.2.5 Association of edentulism and systemic diseases

Evidence is accumulating to support a reciprocal relationship between oral and general health [18, 76-84]. Total tooth loss has well-documented consequences and associations that affect general health in several ways:

1. Lower intake of fruits and vegetables, fiber, carotene and increased cholesterol and saturated fats, which could increase cardiovascular risk [85, 86].

2. Chronic inflammatory changes, *Helicobacter pylori* infection of gastric mucosa and pancreatic cancer [87, 88].

3. Increased risk of death from upper gastrointestinal cancer, heart disease, and stroke [83].

4. Increased rate of non-insulin-dependent diabetes mellitus [89].

5. Elevated systolic blood pressure, hypertension, increased atherosclerotic vascular disease, heart failure, ischemic heart disease and aortic valve sclerosis [80, 84, 90].

6. Decreased daily function, physical activity and physical index of quality of life [91, 92].

7. Decreased self-esteem and a decline in psycho-social well-being and quality of life [93].

8. Increased prevalence of sleep-disordered breathing and edentulous oral dyskinesia, as well as intensified expression of tardive dyskenesia. Edentulism may induce oral dyskenesia that is defined as abnormal, involuntary, patterned or stereotyped and purposeless orofacial movements. Several factors such as ill-fitting and unstable prostheses, oral discomfort, and lack of sensory contacts have been proposed to explain edentulous oral dyskenesia, but the exact mechanism is

still not clear. Edentulous individuals may have additional prosthetic problems as a result of soft and hard tissue damage caused by oral dyskenesia. Edentulous oral dyskenesia must be distinguished from tardive dyskinesia, a type of dyskenesia occurring among patients chronically treated with antipsychotic drugs [94, 95].

9. Increased prevalence of denture stomatitis, oral candidosis and aspiration pneumonia [96-98].

The mechanisms linking poor general health and tooth loss are not yet clear. Many pathways for this association have been postulated, among them the possible mediating role of nutrition. Nutritional factors, especially antioxidants that may decrease following tooth loss, may modulate systemic disease by interfering with the inflammatory cascade and preventing carcinogenesis [99]. A reduced consumption of high-fiber foods is considered as a prime cause of a number of disorders such as cardiovascular diseases, gastrointestinal disorders and bowel cancers [63, 82]. It is reported that each increment of 5% calorie intake from *trans*-unsaturated fat could increase the risk of coronary heart disease by 93%. In contrast, each 10 g increase in total fiber could decrease the risk of coronary heart disease by 20% [100, 101]. A recent study on 83,104 US women [101] showed that diet might partially explain the association between oral health and cardiovascular disease. In this cross-sectional analysis, the edentulous women had dietary intakes associated with an increased rate of cardiovascular disease. These results are supported by a longitudinal analysis on 41,891 adults, which confirms that tooth loss is associated with an increase in the prevalence of heart diseases [80].

Furthermore, excessive intakes of highly processed high fat and carbohydrate foods contribute to obesity and obesity–related diseases such as insulin resistance, cardiovascular disease and hyperlipidemia [14, 70]. The results of the study carried out by Lee et al. [74] demonstrated that edentulism was associated with a weight gains of >5% in one year. Furthermore, a reduced consumption of high-fiber foods could induce the development of gastrointestinal disorders in edentulous elderly subjects. The use of gastrointestinal drugs appears to be higher in edentulous subjects with masticatory deficiency [63]. Also of interest is the fact that edentulous individuals, compared with dentate, are more likely to have peptic or duodenal ulcers [88]. Tooth loss that occurs through poor oral hygiene may be a marker for modified gastrointestinal flora and, consequently, greater nitrosamines which are considered as potential carcinogens [88]. According to Shimazaki [102], the mortality rate of the edentulous elders without dentures was significantly higher than those with 20 or more teeth.

Although many potential confounders may influence the relationship between edentulism and systemic diseases, these investigations demonstrate that there are reasons to be concerned that tooth loss and subsequent changes in diet will increase morbidity among the edentate elderly population [78].

1.2.6 Edentulism and quality of life

1.2.6.1 Definition of quality of life and health related quality of life

Today, there is no consensus regarding the definition of quality of life. Quality of life is often used as an umbrella term, covering various concepts, such as health status,

function, life conditions and others. In general, quality of life (QOL) is defined as an individual's perception of his or her position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations and concerns [103]. Perception of quality of life varies between individuals and is dynamic within them [104]. Quality of life will fluctuate over time, the result of changes in any or all of its component parts [104]. Individuals assess their quality of life by comparing their expectations with their experiences [103]. Therefore, phenomena such as coping, sense of coherence, expectancy and adaptation could influence their judgments about their well-being [104]. Several factors, including functional and psychological, as well as social and environmental, variables have been reported to influence individuals' ratings of their quality of life [105-107]. Quality of life is partly affected by a person's oral health. Perceptions of how oral conditions affect daily function and well-being are referred to as oral health related quality of life [108-112]. Recently, oral health-related quality of life has been widely used in clinical studies as an outcome variable to assess the quality, effectiveness and efficacy of oral health care [20, 108, 110, 111, 113-115].

1.2.6.2 The impact of tooth loss on quality of life

Teeth have an important role in facial appearance, speech and eating ability.

There is overwhelming evidence showing the negative effect of edentulism on oral health quality of life [4, 92, 106, 109, 116-120]. Edentulism negatively influences not only oral function, but also social life and day-to-day activities [121]. Compromised oral function has been linked to decreased self-esteem and a decline in oral health quality of life [68, 116, 122]. Edentulous people with unstable dentures

may avoid certain social activities because they are embarrassed to speak, smile or eat in front of others. Many people develop skills to overcome the limitations of dentures, but some patients are unable to do so [123]. Fisk et al. [124] demonstrated that denture wearers have decreased self confidence, premature aging, altered self-image and altered behavior in socializing and forming close relationships. On the other hand, dentures could improve oral appearance and social interactions of individuals, which might enhance self-esteem and thus contribute to psychological well-being [20, 105]. Variables, including type of treatment, age, sex, and marital status, could explain the variation in ratings of oral health related quality of life and tooth loss [20].

1.2.6.3 Quality of life assessment

Increasingly, it is recognized that patients' perceptions of their health are important in evaluating well being and determining health care outcomes [125]. Measuring health status poses challenges that are not apparent with clinically based outcome measurements. The exclusive use of clinical measures has been generally criticized because they provide little insight into the psychosocial aspects of health and do not adequately reflect the health status, functioning and perceived needs of individuals [43, 126, 127]. In the pursuit of this issue, quality of life assessment is being regarded as an indispensable component for evaluating outcomes of health care.

To better characterize what health-related instruments measure, Wilson and Clearly [128] developed a conceptual model that explains the relationships of different clinical variables related to quality of life. This model was later revised by Ferrans et

al. [129] (Figure 2) and proposes causal associations amongst five types of patient outcome measurements. This model is useful for guiding quality of life research, especially in edentulous individuals, since their quality of life may be affected by both physiological and psychological variables.

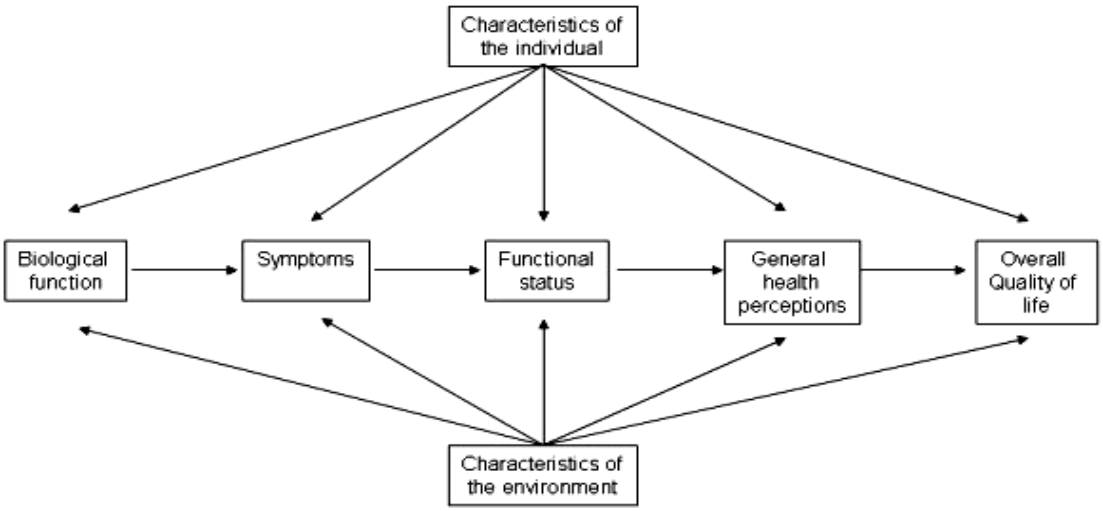

Figure 2. Linking clinical variables with Health Related Quality of Life

Adapted from Revised Model Wilson and Cleary Model for Health Related Quality of life. Ferrans, C.E et al. 2005

A range of multidimensional tools have been developed, validated and used to assess the impact of health on quality of life [130]. Health related quality of life scales have been classified as disease-specific versus generic [131]. Disease-specific scales (Table 2) are used for a specific condition and when greater sensitivity to the clinical condition under consideration is required. These scales recognize aspects of a disease most likely to improve with intervention and consequently, are more responsive to detect changes in outcome resulting from a specific therapy. Generic scales are designed to be applicable across many conditions, since they focus on overall well being. They are used when different relevant variables are covered [112]. The generic and disease specific measures can be used together to capture different elements of quality of life [112]. The Oral Health Impact Profile (OHIP) is a disease–specific measure of people's perceptions of their physical, psychological, and social impacts of oral health on their well-being [130]. This instrument captures seven conceptually formulated dimensions (functional limitation, physical pain, psychological discomfort, physical, psychological and social disability, and handicap). These dimensions are based on Locker's theoretical framework of oral health [30], adapted from the WHO [25]. All attributes for instrument assessment (conceptual and measurement model, reliability, validity, responsiveness, interpretability, respondent and administrative burden, alternative forms, cultural and language adaptations) have been met for the OHIP [132]. Recently, Baker et al., [133, 134] through theoretically driven research, aimed to provide an empirical test of Locker's conceptual model of oral health, as well as the construct validity of the OHIP. They found that, although all of the direct pathways hypothesized by the

model were significant [133], the construct validity of the OHIP scale is open to discussion [134]. However, the investigators of this study agreed that their sample didn't provide an adequate test for the model and that they need to cross-validate their hypothesis using primary data and several samples, rather than secondary analysis with associated bias.

The Oral Health Impact Profile (OHIP) is presented in two formats: Full item and short item versions. The full item version (OHIP-49) has some limitations:

1- It contains a large number of items, which may limit its use in clinical trials and clinical practice. Especially with elders individuals, the instrument should be simple and easy to use. OHIP-49 is time consuming to administer, taking approximately 20 minutes to complete in a young population.

2- Some research questions need a more concise instrument to assess the self-reported impact of treatment outcomes on well-being.

3- Some statements are not relevant for edentulous patients (ex, toothache, sensitive teeth).

The short version (OHIP-14) [135] affects the measurements properties when the sample population is edentulous, because statements relevant to denture wearing were excluded prior to statistical analysis to develop the short version. To overcome these limitations, a modified short version was developed and validated (OHIP-EDENT) [136]. This version is appropiate to use in denture wearers and to evaluate outcomes of prosthodontic treatments for edentulous people. The OHIP-EDENT appears to be sensitive enough to detect differences in OHRQL. The responsiveness to change supports the utility of OHIP- EDENT for clinical studies of edentulous patients and it appears, in general, that domain responsiveness is not influenced by the reduction in the number of items used per domain [137].

One of the most commonly used generic health instruments is the Medical Outcomes Short Form 36 (SF-36). This questionnaire was designed in 1980 to measure the concept of health status and it taps eight health concepts: physical functioning, social functioning, role limitations due to physical health problems, role limitations due to personal or emotional problems, mental health, vitality, pain and general health perceptions [138]. The SF-36 has excellent internal consistency, can discriminate between subjects with and without chronic diseases and can detect moderate treatment effects [138-140]. However, it has been shown that generic instruments, such as SF-36, exhibit limited construct validity and are not sensitive enough to demonstrate changes in oral health. Therefore, it has been suggested that they should be used in combination with a disease-specific scales [131].

Table 2. Oral health outcome instruments ,

Adapted from Locker D and Allen F, 2007.

Social Impacts of Dental Disease (Cushing AM et al., 1986)
General (Geriatric) Oral Health Assessment Index (GOHAI)(Atchison, 1990)
Dental Impact Profile (DIP) (Straus RP, 1993)
Oral Health Impact Profile (OHIP) (Slade DG, 1994)
Oral Impacts on Daily Performances (OIDP) (Adulyanon S, 1997)
Subjective Oral Health Status Indicators (SOHSI) (Locker D,1994)
Oral Health-Related Quality of Life Measure (Kressin NR1997)
Dental Impact on Daily Living (DIDLS) (Leao A, 1994)
Oral Health Quality of Life Inventory (Cornell JE, 1997)
Rand Dental Questions (Dolan TA, 1997)
OHQoL-UK (McGrath C, 2001)
Child Oral Health Quality of Life Questionnaire (COHQoL) (Jokovic A, 2002)
Child OIDP (Gherunpong S, 2004)
OHRQOL for Dental Hygiene (Gadbdury-Amyot CC, 1999)
Orthognathic QOL Questionnaire (Cunningham SJ, 2000)
Surgical Orthodontic Outcome Questionnaire (SOOQ) (Locker D, 2007)

1.2.7 Association of edentulism and oral disease: denture stomatitis

Edentulism can be accompanied by functional and sensory deficiencies of the oral mucosa, oral musculature and the salivary glands. The oral mucosa performs an important protective function. Disorders of the oral mucosa expose the individual to a variety of internal and external pathogens [141]. The prevalence of oral mucosal diseases is an important parameter in evaluating the oral health of an elderly population [141-142]. Although the majority of oral mucosal conditions in the elderly are benign, some may become malignant, especially if the protective functions of oral mucosa are decreased [141]. Decreased tissue regeneration and decreased tissue resistance are expected in this population. Associations have been reported between aging, tooth loss, defective dentures and oral mucosal disorders [141-143]. According to McEntee et al. the odds of finding hyperplasia, stomatitis and angular chelitis increase approximately three-fold in denture wearers [143].

Denture stomatitis is an inflammatory condition of the palatal mucosa seen in complete denture wearers [144-147]. It is generally recognized that it represents the most frequent form of oral candidosis in the elderly [148]. The prevalence of denture stomatitis varies between 6.5% and 75%, depending on the type of sample population [149-155]. Classification of denture stomatitis has been generally based on the type, distribution and extent of the inflammation [144, 153, 156]. Given that no studies showing a cause effect relationship have yet been carried out, there is presently no consensus on the etiologic factors for denture stomatitis [153, 157]. Poor oral /denture hygiene, nocturnal wear of the prosthesis, denture trauma, age of denture, smoking, dietary habits, salivary flow, systemic condition, hypersensivity to denture

base material, bacterial and fungal infection have all been proposed as causal or predisposing factors [144-147, 156, 158-163].

1.2.8 Edentulism and sleep

1.2.8.1 Introduction

Sleep and wakefulness are part of our inherent biological rhythm. Sleep is an active regulated process, which is defined as a reversible behavioural state of perceptual disengagement from and unresponsiveness to the environment [164, 165]. The activity of certain areas of the reticular formation and the reticular nucleus of the thalamus, as well as the locus coerulus and nucleus subcoeruleus, play an important role in the characteristic features of sleep [166].

In the general population, sleep abnormalities adversely affect quality of life-related issues, such as general health status [167], satisfaction with life, mood and work performance [168].

According to several studies, the length and quality of sleep influence mental and physical health [167, 169, 170]. Sleep is necessary for repair of the body and brain, consolidation of memory, maintaining immunocompetence and conserving energy and restorative functions [171, 172]. Patients with sleep disorders show a wide range of manifestations that include insomnia, hypersomnolence, excessive daytime sleepiness, fatigue, snoring, morning headaches, and impaired cognition and attentiveness [173, 174]. These symptoms can result in poor performance at work and an increased rate of automobile accidents.

1.2.8.2 Sleep in elders

Aging affects sleep patterns. The duration, the quality and the efficiency of sleep decrease as we get older. Elders have an earlier sleep onset and morning waking times than younger adults. They are prone to sleep fragmentation and feeling unrested during the day. Total sleep time and sleep efficiency significantly decrease with age [175]. The need for sleep may also be different from younger adults. Sleep architecture is also altered, with an increase in stages 1 and 2 and a decrease in stages 3 and 4. The suppression of slow-wave sleep is based on the reduction of slow–wave amplitude [165, 176]. According to studies by Bliwise et al. [177], by age 60 or 70, stages 3 and 4 account for only 5-10% of total sleep in healthy elderly subjects as compared to 15-25% in adolescents. Usually the REM (Rapid Eye Movement) percentage remains constant through childhood and adulthood, but it does decrease in elders.

It is difficult to define normal and abnormal sleep characteristics in elderly populations, because chronological and physiological age is different for each individual. In addition, conditions such as nocturia and gastroesophageal reflux occur more frequently in the elderly, which may be one cause of nocturnal awakening [177]. Therefore, it is important to be familiar with the differential diagnosis of common sleep complaints of elderly patients. Epidemiological studies have demonstrated that 40-50% of elders have some problem with their sleep [169, 178, 179]. The prevalence of insomnia in elders varies between 19.0% and 38.4% [179, 180]. Difficulty in sleep initiation could be the result of a decrease in the secretory mechanism of certain body chemicals or changes in lifestyle (e.g., edentulism, a change in diet or daytime inactivity) [181].

Sleep disordered breathing appears to be a prevalent condition among elders, with a reported prevalence between 20 to 50 percent [182]. Sleep disorders, such as sleep apnea and periodic leg movement syndrome, have higher rates in elders than in other age groups [169, 183].

Sleep disordered breathing may be due to age-related anatomical modifications [184]. It is caused by partial or complete obstruction of the upper airway. Obesity, increased neck circumference, gender (male sex) and anatomical abnormalities of the face have been reported as risk factors for these diseases [185, 186]. Obstructive sleep apnea syndrome is the most serious sleep disorder in terms of morbidity and mortality [187].

1.2.8.3 The Impact of edentulism on sleep quality

Several studies have noted associations between edentulism and sleep-disordered breathing [95, 188-191]. Anatomical changes associated with edentulism can affect sleep and lead to sleep disordered breathing. These changes include: 1) decrease in the vertical dimension of occlusion 2) change in the position of the mandible and the hyoid bone and 3) impaired function of the oropharyngeal muscles [192, 193].

Reduction in the retropharyngeal space associated with impaired function of the genioglossus and other upper airway dilatation muscles results in upper-airway resistance, which increases the risk of apnea, hypopnea and sleep-disordered breathing. Ten percent of elderly people may show obstructive sleep apnea as a result of edentulism with resulting morbidity and mortality [188, 189].

Gassino et al. evaluated 403 elders and showed that 71% of those who did not wear their prostheses at night were at high risk for sleep apnea. Sleeping without dentures is associated with a significant increase in the apnea-hypopnea index [194, 195]. In a cross sectional study, Endeshaw et al. investigated the relationship between sleep-disordered breathing and denture use [95]. They found a significant association between sleep disordered breathing and denture use. This finding is consistent with a similar study in which subjects had worsening of the Apnea Hypopnea index and decreased antero-posterior oropharengeal wall distance when examined without denture [189]. As two of the major risk factors for this disease are obesity and aging, we can assume that an elderly edentulous patient with a diet on high fat and carbohydrate is more prone to sleep breathing disorder. Moreover, edentulism was reported to have a role in the occurrence or the aggravation of obstructive sleep apnea [189, 194-196].

1.3 Treatment for edentulism

1.3.1 Conventional and implant supported prostheses

Rational treatment planning takes into account the functional and social benefits associated with alternative treatment plans. Treatment decisions should be grounded in evidence-based knowledge, to assure quality and avoid negligent care.

Prosthetic treatment of completely edentulous patients consists of mainly two options: conventional or implant prostheses. Implant prostheses are divided into 2 categories: fixed and removable.

One of the great aims of prosthetic treatment is to enable oral function. Replacing missing teeth with conventional dentures cannot fully offer the efficiency of natural teeth. Thus, the therapeutic paradigm for the treatment of edentulism is shifting from dentures to osseointegrated implant prostheses [197]. During the past few decades, the use of osseointegrated dental implants has provided significant benefits to patients in terms of stability and retention for their prostheses, particularly for the edentulous mandible [197-200]. The chewing ability, as well as patient satisfaction and oral health quality of life, of edentulous individuals improves after implant treatment, regardless of the degree of mandibular prosthetic support (2 *vs.* 4 implants or fixed *vs.* removable prostheses) [4, 198, 199].

1.3.2 The mandibular two-implant overdentures

It is well documented that dental implants stabilize oral prostheses and that these overcome some of the functional limitations of conventional dentures [42, 200-202]. Although replacing old dentures with new well-fitting conventional dentures contributes to improved patient satisfaction [203-206], there is a consensus in the literature that individuals wearing mandibular implant overdentures rate general satisfaction higher than do conventional denture wearers [4, 203, 205, 207, 208].

Some randomized controlled trials studies have reported the positive impact of implant prostheses on oral health related quality of life and general health [20, 123, 205, 206, 209-213]. Fontijn-Tekamp et al. [42, 214] measured bite force and chewing efficiency in subjects with overdentures, with complete full dentures and with natural dentitions. Their results suggest that chewing efficiency achieved with overdentures on dental implants is significantly greater than that of those wearing conventional dentures. Subjects wearing mandibular implant-retained overdentures chewed the food at a faster rate than complete denture wearers.

Recently, it has been agreed that mandibular two-implant retained overdentures should be the minimal standard of care for treating the mandible of edentulous individuals [197]. There are few definitive contraindications for dental implant placement in the anterior mandible (Annex II). However, the cost-effectiveness of treatment and aftercare are important factors for implementation of new therapies. Heydecke *et al.* [215] used a disease-specific health related quality of life index, together with resource-based micro-costing of treatment, to assess the cost-effectiveness of mandibular 2-implant overdentures. They found that provision of this therapy improved oral-health related quality of life by 33%, with an additional expense of $1593. The cost of after care was 3-4% of the total cost at one year follow-up, and the initial costs were the major part of the total costs. Adequate oral hygiene and appropriate after care are essential factors for the long-term success of implant therapy. Abutment design and the type of retentive system (bar, ball, magnet) could influence the need for after care. It is reported that mandibular implant with ball attachments on 2 implants need a higher rate of after care compared to the bar system [216]. This after care usually consists of reactivating matrices, renewing

retention elements, and abutment and screw fracture.

CHAPTER 2

2.1 Research questions, aims and hypotheses

High levels of disability can be reduced through new technology, health promotion and prevention strategies. It is well documented that dental implants stabilize oral prostheses and that this overcomes some of the functional limitations of conventional dentures [4]. Recent literature has underlined the superiority of the mandibular implant overdenture over the conventional complete denture in terms of patient satisfaction and quality of life [4]. However, it is still not clear whether this therapeutic benefit has any long-term positive effects on the oral and general health of elderly populations. Individuals change with time, and the basis on which their health and quality of life is altered may also change [104, 217, 218]. Thus, longitudinal studies are needed to assess the long term outcomes of randomized controlled clinical trials. Furthermore, the influence of continuous wearing of implant overdentures on quality of sleep has never been investigated. In addition, to date no attention has been given to the effect of implant overdentures on oral mucosal health, specifically, denture stomatitis and oral candidosis.

Based on strong pilot data showing that elders wearing mandibular implant overdentures demonstrated significant improvements in serum nutrients and

anthropometric measures [219], Feine et al initiated a randomized clinical trial to compare the nutritional health of edentulous elders wearing mandibular conventional and two-implant overdentures. In this project, this cohort of participants was followed to determine whether treatment with mandibular implant overdentures improves the perceived general health and quality of life of elderly edentulous people on the long term.

Hypotheses

We tested the null hypotheses, that there is no difference in the perceived general health, quality of life, oral health and sleep quality of edentulous individuals who wear mandibular prostheses on two implants with individual ball attachments and those who wear conventional dentures at one year post-delivery.

Primary objectives

To measure the impact of mandibular implant overdentures on the perceived general health and quality of life of edentulous elders one year after they have received their new prostheses.

Secondary objectives

To evaluate the long-term impact of mandibular implant overdentures on prevalence of denture stomatitis, oral candidosis as well as sleep quality.

2.2 Methodology

The sample population was composed of 255 edentulous participants (men and women, 65 years old and over) who were enrolled in a randomized clinical trial (RCT) approved by by the McGill University Institutional Review Board (IRB).

The participants were initially randomized into two groups and received either mandibular overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland) or conventional dentures, both opposed by new conventional maxillary dentures. Standard surgical and prosthodontic procedures (Annex II) were followed, as in previous RCTs undertaken by this research group [203, 212, 213]. Nutritional state, general health and quality of life of all participants were measured at baseline, then at 6 and 12 months following delivery of the prostheses. After the six months follow up, we had planned to follow this cohort for 2, 5, 10 and 15 years. Therfore, after being informed about this follow-up study, each patient who agreed to participate in the follow up, was asked to sign a written informed consent approved by the McGill and the Université de Montréal Institutional Review Boards.

The following outcome variables were gathered through clinical examinations and with validated self-rated questionnaires at one year following delivery of the new prostheses. It is According to Statistics Canada for Quebec, men aged 65 in 2003 could anticipate living, on average, an additional 17.4-years, while women have life expectancy of 20.9 years [220]. Based on age data from 100 participants, we estimate

that 11% will be lost at the 5 year follow-up. To reduce other losses to follow-up, each participant will be contacted at yearly intervals, to ask how they are doing and to remind them about their next visit. This visit will include an oral examination to make sure that they are comfortable with their prostheses.

Primary outcomes

The primary outcome variables were perceived general health and quality of life.

Perceived general health was evaluated through validated questionnaire: SF-36 (The Medical Outcomes Study Short Form-36) [221]. The computerized scoring system used was conducted in this study according to the user's manual (Annex III). Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 represent a better condition. OHIP-20 (Oral Health Impact Profile) questionnaire was used to measure the oral health-related quality of life [130]. The total range of the scale is 20-120 points, with lower scores indicating better oral health-related quality of life. In addition, the Orientation to Life questionnaire (SOC 13) was used to gather variables that may have modifying effects on the OHIP ratings [222].

Secondary outcomes

The secondary outcome variables were prevalence of denture stomatitis and sleep quality. We assessed the sleep quality by using validated questionnaires: the Pittsburg Sleep Quality Index (PSQI) [223], the Epworth Sleepiness Scale (ESS) [224].

Oral health was evaluated through clinical oral examinations by two calibrated clinicians. The findings were categorized and rated according to standard criteria

[153]. Denture plaque was also collected and analyzed in microbiological laboratories in order to detect Candida.

Participants rated chewing ability, speech function, esthetics, retention/stability and ease of use of the dentures on the same validated questionnaires used in the original randomized controlled clinical trial [213]. Subjects received all questionnaires from the research assistant in a secluded area away from the clinic and the care provider.

It was not possible for the participants or the investigator clinicians to be blind to treatment. However, a research assistant who was not involved in the data gathering and who was blind to treatment assignment entered data.

The data were collected and stored for analysis in SPSS version 16 statistical package (SPSS Inc., Chicago, IL, USA). The data were and will be analyzed longitudinally and cross-sectionally.

It is recognized that attrition will occur. Therefore, following the one-year analysis, continuation of the study will be determinated through a futility assessment.

2.3 Contribution to the advancement of knowledge

The findings of this study will be useful for incorporating patient-centred perspective into health care interventions and improving treatment outcomes. Long-term outcomes from treatments, in combination with economic assessments, will provide necessary information for consumers and other payers (government and insurers) to make informed decisions.

2.4 Candidate role on the project

The candidate developed the protocol for the follow up study, incorporated original research hypotheses, set up the study management system and gathered and analyzed data for the first year of the study.

The candidate presented the results of this research project in the annual meetings of the International and American Associations of Dental Research.

Three of the included articles in this thesis have been published or are in press. Three others are in preparation for submission.

CHAPTER 3

Research manuscripts

This chapter includes a series of six articles in which the information gathered through this research project is described.

In the first article entitled "*Research Approaches in Prosthodontics",* we explained the rational of using quantitative approach used in this study. Since patient-based outcomes are individual's concerns of health care and interventions, both quantitative and qualitative research methods are appropriate and feasible method to evaluate these outcomes. Therefore, the quantitative and qualitative research approaches, their differences as well as their advantages and disadvantages are highlighted in this article.

The second article entitled *"The impact of implant-support for mandibular dentures on satisfaction, oral and general health related quality of life: a meta-analysis of randomized controlled trials"* describes a systematic examination of published data on the efficacy of mandibular implant retained overdentures from the patient's perspective.

Finally, the following articles: "*Oral and general health quality of life for edentulous elders wearing two-implant overdentures: results from a one-year randomized trial"*, "*Favoring trauma as an etiological factor in denture stomatitis", "Does sense of coherence influence the outcome of implant therapy? "*, and *"Perceived sleep quality*

among edentulous elders", diffuse the results of this research project and stress the impact of two- implant mandibular overdentures on oral and perceived general health, quality of life as well as perceived sleep quality.

3.1 MANUSCRIPT # 1

Research Approaches in Prosthodontics

Eur J Prosthodont Restor Dent. 2008 Dec;16(4):185-9.

Research Approaches in Prosthodontics

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Abstract

Many current studies of prosthodontic treatment use patient-based outcomes. Traditionally, these outcomes are measured using quantitative methods. However, qualitative research methods can provide important information that cannot be found using quantitative techniques. In this article, the authors review quantitative and qualitative research studies. Differences, advantages and disadvantages of each method are highlighted. Prosthodontic researchers are encouraged to combine these methods to benefit from the potential of each of these approaches.

Key Words: Quantitative, Qualitative, Research approach, Prosthodontic research

Introduction

The impact of prosthodontic therapy on patients has generally been measured by three methods: quantitative, qualitative or a combination of the two [1]. A researcher's choice of measurement approach depends on several factors, including experience and personal training of the researcher, the audience, the type of outcome and, most importantly, the research question [1, 2.]

The aim of this critical review is to provide an overview of common research methodologies and to highlight the main differences between these approaches. An appreciation of these differences is necessary not only to improve the understanding of different research strategies, but also to encourage the use of appropriate approaches to address different research questions, particularly in the field of Prosthodontics.

A search of publications indexed in MEDLINE (1966 to week 3, May 2007), EMBASE (1980 to week 3, May 2007) and CINAHL, plus a search by hand using the keywords "qualitative research and Prosthodontics" yielded 9 articles [3-11] in which qualitative approaches are used and seven articles with mixed approaches [12-18]. In contrast, more than 100 studies have used quantitative methods to measure the impact of prosthetic therapy on patient related factors like satisfaction and quality of life [19]. In order to delineate the methodological disparities in prosthodontic research and to highlight the advantages and disadvantages of each approach in this field, we need to briefly discuss the fundamental differences between qualitative and quantitative research (Table I).

Definitions

The term "quantitative" refers to a tradition of research, dominant in science since the 17th century, that emphasizes the measurement and quantification of phenomena [20]. The

term "qualitative" research is concerned with the nature or quality of human experiences and what these phenomena mean to individuals [21]. According to Creswell [22], "Qualitative research is an inquiry process of understanding based on distinct methodological traditions of inquiry that explore a social or human problem. In qualitative approaches the researcher builds a complex, holistic picture, analyzes words, reports detailed views of informants and conducts the study in a natural setting. Alternatively, quantitative research is an inquiry process based on testing a theory through chosen variables that are measured with numbers and analyzed with statistical procedures in order to determine whether the predictive generalization of the theory holds true [1]".

Qualitative research aims to understand the participant viewpoint, providing rich descriptive detail that sets quantitative results into the human context [23]. Results from qualitative studies can be published on their own. For example, Omar *et al.* [24], used qualitative methods to study the emotional effects of tooth loss and the influence of religious beliefs in coping with the psychological impact of tooth loss. In addition, qualitative research can complement quantitative research by expanding the information gained through quantitative research, ie as a hypothesis generating [25].

Differences between qualitative and quantitative approaches

The main difference between quantitative and qualitative approaches is the research question. Qualitative research allows the researcher to generate hypotheses and to define research questions throughout the research process, while quantitative research requires the hypotheses prior to the start of the study. Qualitative approaches document an individual's experiences and feelings in an attempt to characterize the complexity of human experience. In addition, one of the powerful tools of qualitative research is reflexivity, which permits researchers to develop ideas and negotiate relationships, thereby influencing the collection and analysis of data as the study progresses. This information could be very useful for other investigators, such as public health policy makers. For them, qualitative research is an important tool to study the "black box" and to understand the factors that contribute to success or failure of health care policies [26].

Differences between qualitative and quantitative approaches reflect also in each step of the research process, as described by Creswell[1, 2] and summerize below. Knowledge of these differences provides valuable information for understanding the aims of each approach.

Step 1: Identifying a Research Problem

Quantitative Research: The research problem requires a description of trends or an explanation of a relationship amongst variables [1, 2].

Qualitative Research: The research problem requires an exploration and understanding of a central phenomenon because of a lack or inaccuracy of theory. The researcher needs to learn more from participants [27]. The nature of the phenomenon may also not be suited to quantitative measures [28].

Step 2: Reviewing the Literature

Quantitative research: The literature review has an essential role to justify the need for research and to provide direction for the research question or hypothesis. Based on the literature, the researcher identifies important variables and potential relationships that need to be examined[1].

Qualitative Research: As in quantitative research, the literature review justifies the need for research on the topic. However, as opposed to quantitative research, the review does not provide direction. The direction of the research is provided by the information supplied by the study participants [2].

Step 3: Specifying a Research Question

Quantitative Research: In order to obtain measurable and observable data on variables of interest, the research questions and hypotheses are specific and narrow [2]. Quantitative questions ask about frequency, performance, time, location, intensity, strength and sequence, and groups are compared or a relationship between variables are established through association or cause-effect [29].

Qualitative Research: The research question often starts with how or what, so that it forays into the topic and describes what is going on. Research questions and hypotheses are general and broad, thus evoking needed information to synthesize and prioritize observations about behaviours [20].

Step 4: Choice of outcomes and instruments; Data collection

Quantitative Research: An enormous array of instruments, either ad hoc or standardized, are used to measure the impact of prosthetic therapy, including the Oral Health Impact Profile (OHIP) [30], the SF-36 [31], and others [32]. These instruments differ in their primary intended purpose and in their content. The rationale for using a measure should be clear and justified according to the target population and the context in which it is used. It should be appropriate, reliable, valid, responsive, precise, interpretable, acceptable and feasible. These instruments permit the collection of numerical data, which, in turn, permits quantitative statistical analyses. The aim of this process is to generalize information from a small number of people to a larger population. Thus, the sample should be representative and large enough to show differences between the variables.

Choice of outcomes

Patient-based versus clinician-based outcomes

The literature confirms that there is a discrepancy between clinical findings or the perceptions of clinicians and patients' perceptions of pain or treatment satisfaction [33]. Thus, in order to evaluate interventions and to identify more appropriate forms of health care, particularly for chronic conditions, it is necessary to take into account patients' judgments and preferences.

A number of roles have been suggested for patient-based outcome measures including: their use as screening tools, as methods to identify patient preferences, to help clinicians make informed decisions, and as a means to improve patient–provider communication [34]. Patient-reported outcome measures aim to capture the patients' perspective of health, illness, and the effects of health care interventions in a reliable, valid, acceptable and feasible way.

Alternatively, clinical scales are the perceptual judgement of health professionals. Some researchers prefer clinical and laboratory based data and argue that they are more "objective", easier to quantify, easily reproducible and clinically relevant for determining treatment effectiveness. However, these are measurements of technical issues that could be independent of patient judgment. Therefore, their use should be to understand more about technical issues and not used to substitute for indicators of treatment success.

Qualitative Research: Qualitative data typically consist of text or image data. The researcher does not start data collection with a set of tools to measure different variables. Instead, the researcher learns from the participants in the study and develops a form for data recording as the study proceeds [35]. There are wide arrays of data collection techniques and most fall into three categories that include in-depth interviews, observation or existing documents [2]. The objective of the interview is to explore the ideas of the interviewees about the phenomenon of interest. In observational protocols, the behaviour of participants is also noted. The data can be collected from the existing documents like newspapers and websites, audio, video or pictures. From audio-recordings, transcripts of text are typed to form a database. In this approach, the investigator does not use instruments constructed by other researchers. Instead they develop their own form of interview protocol [2].

Step 5: Analyzing and Interpreting the Data

Quantitative Research: Data are analyzed by statistical procedures and interpreted according to initial predictions or prior studies.

Qualitative Research: A text database is analyzed by being divided into groups of sentences. The analysis procedure consists of determining the meaning of the text segments and description of the central phenomenon under investigation. This description includes contextual information about the people or idea being studied. The data analysis reflects the

description and thematic development as well as interrelation of themes. The researchers reflect on their own bias, values and assumptions and discuss their role, their experiences, and their cultural backgrounds [2, 36]. The interpretation is an explanation of how the findings relate to the research and a personal reflection about the significance of what has been learned during the study [2].

Mixed approaches

Although a long-standing debate has existed between qualitative and quantitative methodologists about which of these methods are most valid, health researchers recently have begun to understand the benefits of booth tools and are now combining the two methods [12, 37]. This mixed approach allows confirmation of findings from different data sources [1]. For example, exploration of potential outliers with in-depth interviews can provide insight about their divergence [1, 25, 38]. Sondell *et al.* [17] has carried out mixed approach studies to evaluate the influence of verbal communication on patient satisfaction with prosthodontic treatment. They showed that giving the patients an opportunity to discuss their dental health improved their satisfaction with the treatment outcome. Finally, mixed methods permit researchers to both generalize findings to a population and to develop a detailed view of the concept on an individual basis.

Research approaches used in Prosthodontics

Incorporating a device into the oral cavity is a complex process. A variety of factors contribute to how much each patient benefits and how she/he adapts to the prosthesis. Physical and physiological factors include chewing ability, oral health status, and diet and nutrition [39-43]. Psychological and behavioural factors include patient expectations, self-

esteem, quality of life and social relationships [44-46]. Investigators have measured these various factors using patient-based [47-51], clinician-based and laboratory-based instruments [43, 52, 53].

In Prosthodontics, the discrepancy between professionally- expressed and patient-expressed needs has forced clinicians to accept that, although Prosthodontics is a technical science, technical skills alone are not good predictor of patient satisfaction with treatment. Therefore, the use of patient-based outcomes to measure the impact of prostheses on well-being have increased over the last decade [47], especially in the field of removable Prosthodontics, which essentially involves social, psychological and physical impacts of edentulism. Even when using patient-based measures, prosthodontic research involves primarily quantitative approaches because of the following issues:

When used appropriately, the internal and external validity of both qualitative and quantitative methods has never been in doubt, but the credibility and respectability of these methods vary across disciplines, professions, time periods and countries [54]. The credibility of the researcher depends on several factors such as training, experience and philosophical beliefs of the value of the qualitative inquiry [54]. As a consequence, qualitative research is either absent or poorly ranked in methodological hierarchies of scientific evidence [55]. Furthermore, fundability of qualitative research in the prosthetic field is challenging because approaches that produce analytical data tend to be favoured by policymakers and those who fund research. This is because findings that are easily generalizable appear to be more suitable for practical application and justification of difficult clinical and political decisions. In addition, a rigorous qualitative research that provides in-depth descriptions and observations usually requires greater amounts of time, labour and cost than similar quantitative investigations [17, 56].

Quantitative research can be replicated with ease and confirmed or refined in follow-up studies. The data obtained from quantitative research has the advantage of being amenable to highly sophisticated statistical analyses and modeling procedures. Moreover, systematic reviews of quantitative data appear to be less susceptible to bias from external influences than reviews of qualitative data. Systematic reviews of quantitative data do not involve personal feelings, and researcher objectivity is assumed [57]. On the other hand, qualitative analysis depends on the insights and conceptual capabilities of the analyst.

However, qualitative research can provide insight into phenomena that have not been previously studied. Qualitative research defines and answers questions that quantitative methods cannot address [58]. For example, would soldier who has lost part of his body during combat value a dental prosthesis more than a Hollywood star? Answering this question requires an understanding of the social environment, thoughts, feelings and experiences of the people involved. The effects of intangibles such as beliefs, the complexity of human interaction and understanding how the social, political and economic context influences human experiences and behaviours can provide clinicians with a better understanding of the impact of their prosthetic therapies.

Conclusion:

Qualitative and quantitative research studies follow completely different strategies and design elements. The crux of good research is the appropriate use of different methodologies. To truly assess the range of prosthodontic outcomes, one must consider the physiologic, psychologic and social implications. Thus, creative study designs that adopt methodological pluralism are encouraged.

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Table 1: A comparison of several key characteristics of qualitative and quantitative approaches. Adapted from Jack (2006)[26], Creswell (2003)[1, 22].

	Qualitative	Quantitative
Philosophical Basis	Naturalism, interpretivism Acceptance of multiple realities Subjectivity	Materialism and positivism Acceptance that only one reality exist Objectivity
Aim	To search for understanding and meaning To define research question To generate new theories or hypotheses To explore contextual influences on phenomena To identify themes relevant to specific context that may be transferable to other settings	To test or verifies hypothesis and establish laws of cause and effect, association or correlation To generalize finding to a population
Methodological Underpinnings	Inductive processes Researcher is the primary instrument Flexible design Difficult to confirm sample size a priori Open ended questions Interpretation of phenomena emerge from participants' experience	Deductive processes Hypothesis testing Instrument based question Fixed design with predetermined sample size Close ended questions Statistical analysis
Research Designs [22]	Grounded theory Phenomenology Ethnography Case study Participatory action research	Experimental, quasi-experimental and observational Ex: RCT, Cohort studies, case control

3. 2 MANUSCRIPT # 2

The impact of implant-support for mandibular dentures on satisfaction, oral and general health related quality of life: a meta-analysis of randomized controlled trials

Clinical Oral Implant Research: In press

The impact of implant-support for mandibular dentures on satisfaction, oral and general health related quality of life: a meta-analysis of randomized controlled trials

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Key words: systematic review, meta-analysis, randomized clinical trial, implant overdenture, patient satisfaction, oral and general health related quality of life

Abstract

Objectives:

The aim of this study was to systematically examine the data published on the efficacy of mandibular implant retained overdentures from the patient's perspective.

Material and Methods:

Medline, Embase, The Cochrane Central Register of Controlled Trials and The Cochrane Systematic Reviews Database were searched and complemented by hand searching. Included were all randomized controlled trials published in English or French up to April 2007, in which conventional dentures and mandibular implant overdentures in adult edentulous individuals were compared. The outcomes of interest were patient satisfaction, oral and general health related quality of life. Random effects models were used to pool the effect sizes of all included studies.

Results:

Ten publications of 7 randomized controlled trials were identified and eight were included in the meta-analysis. When compared with mandibular conventional dentures, implant overdentures were rated to be more satisfactory at a clinically relevant level (pooled effect size 0.80, z= 3.56, 95% confidence intervals (CI) 0.36 to 1.24, P=0.0004) but statistical heterogeneity was founded (Chi^2=31.63, df=5 P<0.00001 I^2=84%). The pooled effect size for oral health quality of life was -0.41 (z= 1.31 95% CI, -1.02 to 0.20; P=0.19, Chi^2=11.53, df=2 P<0.003 I^2=83%). There was a lack of evidence to show the impact of mandibular implant overdenture on perceived general health.

Conclusions:

Our findings suggest that, although mandibular implant retained overdentures may be more satisfying to edentulous patients than new conventional dentures, the magnitude of the effect is still uncertain. There is a need for additional evidence including cost-effectiveness analyses on the impact of mandibular implant overdentures and conventional dentures.

Introduction

Dependence on removable dentures is still a reality of life for millions of people all around the world (Douglass et al. 2002, Petersen et al. 2005). Conventional complete denture wearers experience a variety of daily problems, such as instability of their mandibular dentures, inability to comminute foods, decreased self confidence, decreased quality of life and decreased social contact and satisfaction (Redford et al. 1996). One of the major goals in health promotion is to develop new technology that addresses these daily problems. Although in recent years, the positive impact of implant therapy on patient-based outcomes has been shown (Allen & McMillan 2003, Awad et al. 2003b, Geertman et al. 1994), there is a controversy regarding the best prosthetic treatment for edentulous patients (Burns 2000, Feine et al. 2002, Fitzpatrick 2006, Strassburger et al. 2006).

Therefore, a systematic review might shed some light on this topic. This study aimed to assess the efficacy of mandibular implant retained overdentures from the patient's perspective through a systematic review and meta-analysis. It focused on the question: do edentulous individuals who wear mandibular conventional dentures or implant retained overdentures rate their general satisfaction, oral and general health quality of life differently? Our hypothesis was that there is no difference in general satisfaction, oral health quality of life and perceived general health between conventional denture wearers and those wearing mandibular implant retained overdentures.

Material and methods

The structure of this report is based on guidelines proposed at the Quality of Reporting of Meta-Analyses (QUOROM) conference (Moher et al. 1999a).

Search strategy and eligibility criteria

We conducted a systematic literature search until April 2007 of MEDLINE from 1966, EMBASE from 1980, The Cochrane Central Register of Controlled Trials and the Cochrane Systematic Reviews Database. We included all relevant randomized controlled trials in which edentulous individuals aged 18 or older wearing maxillary conventional dentures and either mandibular implant retained overdentures or conventional dentures rated general satisfaction and general and oral health related quality of life with a follow up period of at least 2 months. The exclusion criteria for this study were randomized controlled trials without conventional denture wearers as a control group, insufficient data that could not be rectified by imputation or author contact or outcomes of no interest to this review. Quasi-randomized trials were not included. Study populations that appeared in more than one publication were included only once in meta-analysis, using the more informative publication regarding the outcome of interest.

We developed a detailed search strategy for Medline (PubMed), and then revised for each the other 3 data bases. We created groupings of words which were internally combined with the Boolean term “OR”. The first group consisted of the terms:

denture, complete denture, complete lower dental prosthesis, dental prosthesis, implant supported, implant overdenture, overdenture, dental implantation and dental implant. The second group contained the terms related to the outcomes of interest: health, general health, oral health, patient satisfaction, quality of life, outcome assessment, outcome and process assessment, treatment outcome, health status, health status indicators, public health, mental health, oral hygiene, SF-36, OHIP and physical activity scale. These two groups of terms were then combined using the Boolean term "AND". The search was run with Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); PubMed format. Language was not restricted.

We identified additional studies from the reference lists of articles retrieved in this manner and performed a hand search of all issues of *British Journal of Oral and Maxillofacial Surgery*, *Clinical Oral Implants Research, Implant Dentistry, Community Dentistry And Oral Epidemiology, International Journal of oral and maxillofacial surgery, The International Journal of Prosthodontics, International Journal of Periodontics and Restorative Dentistry, Journal of Oral Maxillofacial Surgery, Journal of Dentistry, Journal of Dental Research, Journal of Oral Implantology, Journal of Oral Rehabilitation, The Journal of Prosthetic Dentistry, The International Journal of Oral & Maxillofacial Implant*s, that were published over the past 5 years, as well as abstracts from International Association of Dental Research meetings . In addition, we wrote to clinical researchers and implant manufacturers to request any data they held from unpublished trials.

Two reviewers (E. E. and G. H.) independently screened the titles and abstracts of each citation and identified all citations for full review if there was any possibility that the study contained the comparison of interest. Intra-examiner calibration at the beginning of the systematic review and duplicate examinations throughout study collection were carried out. Kappa values were 0.83 and 0.86, respectively, indicating a high and consistent agreement. Disagreement between reviewers was discussed and resolved by consensus. The full copy of all possibly or definitely relevant studies was retained for further assessment. The search procedure and reasons for exclusion of studies are shown in Figure 1.

Assessment of methodological quality

This assessment used a domain-based evaluation, including reports of sample size estimation and parameters of quality: sequence generation, allocation concealment, completeness of follow up and intention-to-treat analysis.

The quality of included studies was assessed following the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green 2008). We graded each parameter of trial methodological quality as: “adequate”, “inadequate” and “unclear or not reported”:

1. Sequence generation was evaluated as “adequate”, if it included any one of the following methods of randomisation: computer generated or table of random numbers, drawing of lots, coin-toss, shuffling cards or throw of a dice. It was judged as “inadequate” for methods of randomisation utilising any of the following: case record number, date of birth, or alternate numbers.

2. Concealment of allocation was graded “adequate” if methods of allocation concealment included either central randomisation or sequentially numbered sealed opaque envelopes. This criterion was considered “inadequate” if there was an open allocation sequence and the participants and trialists could foresee the upcoming assignment.

3. The handling of withdrawals and losses was assessed according to whether there was a clear description given for withdrawals and drop outs in each treatment group.

Assessment of intention to treat analyses was based on 2 criteria:

1. That all participants were analysed with the groups to which they were randomized, regardless of which treatment they actually received;

2. That all participants were included, regardless of whether their outcomes were collected.

Masking outcome assessors, blinding of care providers or participants was not feasible in these trials and, hence these aspects were not used as measures of study quality.

Data extraction and outcomes

From each study, we collected the following data: authors, country, years of study, study design, recruitment methods, population characteristics and sampling criteria, randomisation method, number randomized, intervention characteristics, main outcomes (general satisfaction, oral and general health related quality of life), type of measurement instrument, baseline and post treatment scores, follow up period and

dropout percentage. Additional information was sought from authors when necessary.

Data were abstracted by one investigator using a data extraction form, and then were checked by the other investigator.

Statistical analysis

All analyses were performed using Review Manager Version 5.0 software (Cochrane Collaboration 2008). Only studies of similar comparisons reporting the same outcome measures were included in the meta-analysis. Studies included in this meta-analysis were also required to have a minimum follow-up time of 2 months.

Effect sizes (ES) were calculated to compare results across studies. Effects were expressed as standard mean differences (SMD). SMD standardize the measurements on a uniform scale. The magnitude of an ES has been described by Cohen; 0.3 represents a small effect, 0.5 a medium effect, and 1.0 a large effect (Cohen 1988). When medians were presented, the values were converted to means (SD). Differences in the direction of scales were adjusted by multiplying the mean values by -1. Data extracted from visual analogue scales were transformed to Likert-type scales.

The analyses were carried out using a random effect model that accounts for inter-study variation and provides a more conservative estimate than a fixed model (Higgins & Green 2008). The Cochrane Q test and I^2 statistic were used to test heterogeneity between the trials. I^2 approximates the proportion of total variation in

the effect size that is due to heterogeneity, rather than sampling error. An α error p<0.20 and I^2 of at least 50% were taken as indicators of heterogeneity of outcomes. To explore sources of heterogeneity across the studies, we planned to conduct *a priori* subgroup analyses according to recruitment method (general population recruited via advertisement, participants with poor oral condition and severe problem recruited via referral to specialist clinics). When comparisons were made between pooled standardised mean differences, statistical differences were assessed using a *Z* test, $P< 0.05$ was considered significant. Funnel plots were used to assess potential retrieval bias (Petitti 2000).

Results

Characteristics of trials, patients and interventions

In total, 2262 non duplicate articles were identified from database searches, of which 37 were eligible for full text searching (Figure 1). Any unpublished data were found by contacting the companies or investigators; all missing data were rectified through author contact. All of the studies were published in English. Of these, 27 papers were excluded because: 1) they didn't meet the inclusion criteria; 2) their population or their outcome overlapped with other papers in the review; 3) they used outcomes of no interest in this review (Awad & Feine 1998, Awad et al. 2000b, Boerrigter et al. 1995a, Esfandiari et al. 2006, Fontijn-Tekamp et al. 1998, Fontijn-Tekamp et al. 2001, Fontijn-Tekamp et al. 2004, Garrett et al. 1998, Geertman et al. 1994, Geertman et al. 1999, Hamada et al. 2001, Heydecke et al. 2003a, Heydecke et al. 2003b, Kapur et al.

1998, Kimoto & Garrett 2003, MacEntee et al. 2005, Meijer et al. 1999, Morais et al. 2003, Raghoebar et al. 2003, Ring et al. 2005, Roumanas et al. 2003, Roumanas et al. 2002, Stellingsma et al. 2005, van Kampen et al. 2002, van Kampen et al. 2004, Visser et al. 2006, Walton et al. 2002).

A total of 10 manuscripts on 7 randomized controlled trials were included in this review. Details of the characteristics of each trial are shown in Table 1. The earliest study was published in 1995 (Boerrigter et al. 1995b), and the last in 2006 (Allen et al. 2006). All included trials used a parallel design with two arms, except for one trial with three arms (Bouma et al. 1997). One study was a multicenter, randomized clinical trial (Bouma et al. 1997, Meijer et al. 2003). Other publications stemming from this multi-center trial were excluded because of the same population.

The unit of allocation chosen was each individual in all of the trials. The trials varied by recruitment methods, inclusion criteria, sample size, population characteristics, implant and retention systems and follow up durations. Participants were recruited in 3 different ways: 1) patients with severely resorbed mandibles and severe problems with their dentures, referred by their general practitioners to university hospitals or prosthodontic departments (Allen et al. 2006, Boerrigter et al. 1995b, Bouma et al. 1997, Meijer et al. 2003); 2) controlled diabetic patients from medical centers with varying degrees of satisfaction with their existing conventional dentures (Kapur et al. 1999); 3) general population recruited via newspapers advertisements (Awad et al. 2000a, Awad et al. 2003a, Awad et al. 2003b, Heydecke et al. 2005, Thomason et al. 2003).

Complete edentulousness in the maxilla and mandible for at least one year (Boerrigter et al. 1995b, Bouma et al. 1997, Meijer et al. 2003), five years (Allen et al. 2006, Awad et al. 2003b, Thomason et al. 2003), 10 years (Awad et al. 2000a , Awad et al. 2003a, Heydecke et al. 2005), adequate bone support and no medical contra-indications for dental implants or surgical procedures were common inclusion criteria in all trials. In some studies, a specified minimum mandibular bone height (variation between 8 to 25 mm) was one of the inclusion criteria (Boerrigter et al. 1995b, Bouma et al. 1997, Meijer et al. 2003).

The sample sizes in these trials varied from n=60 to n=157 participants. For all trials, the groups seemed comparable at baseline with respect to primary outcomes. All trials were conducted at University dental clinics or hospitals, except one in which the participants were treated at a Veterans Affairs Medical Center (Kapur et al. 1999). All dentures were made by prosthodontists or senior prosthodontic residents.

Participants assigned to the implant groups received various implant systems, including the Branemark System (Nobel Biocare, Nobelpharma, Sweden), the IMZ System (Friadent, Freidrichsfeld AG, Interpole International Germany), the ITI system (Straumann Switzerland) or the TMI system (Krijnen medical BV, The Netherlands). Two implants were placed in the interforaminal region of the mandible in all trials, except in one trial in which a group received transmandibular implants (Boerrigter et al. 1995b). Overdentures were retained by clip attachment to a bar or two ball attachments. In all trials, participants received conventional maxillary dentures.

The follow up periods ranged from 2 months to 10 years. The dropout rate ranged from a minimum of 4% at 2 months to a maximum of 55% at 24 months follow up (Table 1).

Methodological quality of the trials

A sample size estimation was carried out and reported for all, except three of the trials (Boerrigter et al. 1995b, Bouma et al. 1997, Meijer et al. 2003). It has been shown that 26 edentulous subjects per treatment group would provide 80% power with a type I error of 0.05, for a clinical meaningful difference of 20 mm (SD 27) in general satisfaction measured on a 100-mm visual analogue scale. Thus, the sample sizes of these three studies should be sufficiently large for clinically meaningful differences to be detected (Awad et al. 2003b, Thomason et al. 2003).

A summary of the quality of the included trials based on sequence generation, allocation concealment and completeness of follow up is presented in Table and Figure 2. The trials were different in their methods of randomized sequence generation. They included balanced allocation (Boerrigter et al. 1995b, Bouma et al. 1997, Meijer et al. 2003), block randomisation (Awad et al. 2003b, Thomason et al. 2003), computer generated random numbers (Allen et al. 2006) and stratification (Awad et al. 2000a, Awad et al. 2003a, Heydecke et al. 2005, Kapur et al. 1999). Some trials reported masking for staff who assisted in gathering the data (Awad et al. 2003b, Bouma et al. 1997, Heydecke et al. 2005, Kapur et al. 1999, Thomason et al. 2003). A large number of trials reported that analyses were carried out on an ‘intention to treat ’ (ITT) basis (Allen et al. 2006, Awad et al. 2000a, Awad et al. 2003a, Awad et al. 2003b, Boerrigter et al. 1995b, Thomason et al. 2003). However,

many trials were reported to have included ITT analysis when they actually met only the first of the two criteria for a proper ITT analysis: All participants were analysed with the groups to which they were randomized, but the drop outs after randomization were not included (Allen et al. 2006, Awad et al. 2003b, Boerrigter et al. 1995b). Statistical analyses were adequate in all of the studies.

Effect of type of mandibular prosthesis on patient satisfaction

A summary of the retrieved literature on the effect of mandibular prostheses on patient satisfaction is presented in Table 1. From a total of ten, six studies with 588 participants (n=322 implant overdentures n=266 conventional dentures) were included in the meta-analysis. Participants' general satisfaction with their prostheses was assessed using 100-mm visual analogue scale (VAS) or Likert-type response scales. Standardized mean differences were positive in all of the studies (Figure 3). The pooled ES was 0.80 (z= 3.56, 95% confidence intervals CI 0.36 to 1.24, P =0.0004) in favour of implant overdenture treatment. The P value for heterogeneity (Chi^2 =31.63, df=5) was P <0.00001 and I^2=84%. (Figure 3 analysis 1.1.1). Two studies (Allen et al. 2006, Kapur et al. 1999) had a 95% confidence interval that included an ES of zero. The overall standardised mean difference for the general population recruited via newspaper advertisements was 0.81 [z= 4.95 (95% CI 0.49, to 1.13 P <0.00001); test for hetrogeneity P =0.70, I^2=0%.] (Figure 3, analysis 1.1.2). For participants who were referred to specialist clinics because of their poor oral condition or severe problems with their dentures, the overall standardised mean difference was 0.95 [(z= 2.31 95% CI 0.14, to 1.75 Chi^2 =25.30, df=2 P = 0.02); test for hetrogeneity P <0.00001, I^2=92%] (Figure 3, analysis 1.1.3). In one study (Kapur

et al. 1999), in which participants were controlled diabetic patients referred from medical centers, the overall standardised mean difference was 0.30 [(z= 1.19 95% CI -0.19, to 0.80 P = 0.23)] (Figure 3, analysis 1.1.4).

2. Effect of type of mandibular prosthesis on oral health related quality of life

The summary results of the studies evaluating the impact of mandibular prosthesis on oral health related quality of life are presented in Table 1.

The meta-analysis includes only the studies using the oral health related quality of life as outcome. Thus, we included only studies using OHIP as measurement instrument, and excluded two others (Bouma et al.1997, and Heydecke et al. 2005). The instruments used in these two studies were: The Groningen Activity Restriction Scale-Dentistry (GARS-D), the Psychological Well Being Scale for Denture Patients, the Hopkins Symptom Check List (HSLC), the Linear Analogue Self-Assessment (LASA), and the Social Impact Questionnaire. These instruments have been used to measure the impact of oral prostheses on individuals' psychosocial well-being, general quality of life and on social and sexual activities.

For all 3 trials combined, the pooled effect size was -0.41 (z= 1.31 95% CI -1.02 to 0.20; P=0.19). Significant heterogeneity was observed (Chi^2 =11.53, df=2 P =0.003 I^2=83%; Figure 4 analysis 1.2.1). In 2 of the 3 included trials, the 95% confidence intervals didn't include an ES of zero, which is consistent with a positive effect (Awad et al. 2000a, Awad et al. 2003b). When analyses were restricted to studies that included participants from the general population who were recruited via advertisement, the pooled ES fell from -0.41 to -0.71 (z=4.37 95% CI -1.03 to -0.39;

P<0.0001), revealing significant post treatment differences in favour of the implant overdenture treatment. For these studies, heterogeneity (Chi^2 =0.11, df=1, P =0.74, I^2=0%) was rejected (Figure 4, analysis 1.2.2). The trial of Allen et al. (Allen et al. 2006) showed a nearly null result (Figure 4 analysis 1.2.3).

3. Effect of type of mandibular prosthesis on perceived general health

The lack of evidence in this field was conspicuous. We found only one article (Heydecke et al. 2003a) in which perceived general health was measured with a generic instrument, The Short Form (SF-36). Based on a reverse scoring system, they found no difference between the conventional denture and the implant overdenture groups on any of the SF-36 subscales. Since this was the only article using a reverse scoring method, further processing of the data was not performed.

Publication bias

We were unable to find studies (published or not published) in which negative effects were found. The funnel plot is not included in this report, because less than 10 RCTs are available. In these situations the test for asymmetry is not powerful enough to distinguish chance from real asymmetry (Higgins & Green 2008).

Discussion

This meta-analysis yielded two principal findings. Firstly, the results of this meta-analysis demonstrate that mandibular implant overdentures might be a more effective

treatment for edentulous individuals than conventional dentures, based on patient ratings of satisfaction or oral health related quality of life. However, there is still uncertainty about the true magnitude of the effect.

Secondly, there is a lack of evidence concerning the impact of mandibular two-implant overdentures on perceived general health.

To our knowledge, this is the first systematic review and meta-analysis on this topic, in which only randomized controlled trials were included. Strengths of this study include the sole use of randomized controlled trials and the inclusion of patient based outcomes. Unbiased evidence obtained from systematic reviews of individual randomized trials is needed to estimate the effect of healthcare interventions and to determine whether there are differences in their effects. However, some limitations should be considered when interpreting these results. Despite our extensive search strategy, the number of included randomized controlled trials was limited. This could partly have been caused by the fact that some trial results may not have been reported due to negative findings. Furthermore, our analysis was limited by any flaws in the methodological quality of the included trials, which could threaten the internal validity of the study and introduce risk of bias. In fact, this meta-analysis revealed substantial statistical heterogeneity. However, it is not surprising to find this incompatibility in quantitative results since the studies in any meta-analysis will necessarily be clinically heterogeneous (Hardy & Thompson 1998). Trials included in this meta-analysis differed in patient recruitment, patient characteristics, duration of follow up, the extent of withdrawals and the handling of losses to follow up. Other source of heterogeneity could be also the result of ignoring the quality of component trials (Schulz et al. 1995). We used a component approach to assess the trial quality in

this study, since the use of composite scales has been reported to be problematic for several reasons, including items not related to the internal validity of the trial (Jüni et al. 1999).

Although randomized controlled trials are the accepted gold standard in the evaluation of the effectiveness of health care interventions, they are not immune to bias. In fact, several studies have shown that trial quality has an impact on the effect size (Moher et al. 1998). It is reported that poorly concealed treatment allocation is associated, on average, with an exaggeration of treatment effects by 20% to 40%. Trials that are not double blinded also result in larger effect sizes (Schulz et al. 1995). The quality assessment of studies included in this meta-analysis indicated unreported allocation concealment in all of the publications. We recontacted the authors to clarify the level of allocation concealment. Based on the explanations of allocation concealment by those who responded, it appears likely that the allocation concealment was adequate in these trials, even though these details were not originally conform to Cochrane guidelines. Furthermore, in none of the included trials was double blinding carried out. However, the quality of randomized controlled trials in implant research must be assessed with consideration of the nature of the condition. In other words, loss of dentition is a chronic condition, and therapies for complete tooth loss are palliative. As with all palliative care, the aim is to improve function, quality of life and patient satisfaction. Therefore, patient based outcomes are most appropriate outcomes, and blinding is often not possible. This means that no implant studies can be considered to meet the quality "gold standard", since the criteria is that the study is double blinded. Therefore, the results of implant studies should be interpreted with caution, because of this risk of bias. In addition, overestimation of the results should be considered.

Three systematic reviews that include a variety of study designs (Fitzpatrick 2006, Strassburger et al. 2006, Thomason et al. 2007) addressed the impact of implant prostheses on patient based outcomes, including patient satisfaction and quality of life. The latest (Thomason et al. 2007), carried out by the European Workshop on Evidence-Based Reconstructive Dentistry, concluded that the magnitude of the treatment effect is greater for mandibular implant overdentures than for conventional dentures. However, the other two reviews indicated that complete dentures are still a good treatment choice for people who are able to adapt to these devices (Fitzpatrick 2006, Strassburger et al. 2006). These authors also concluded that implant overdentures are more beneficial to patients with advanced alveolar bone resorption and those with several denture problems. However, the Fitzpatrick (2006) review does not meet the criteria of standard systematic reviews. In this article, search strategy, results and conclusions appear to be drawn from selective analyses. Strassburger et al.(2006) reviewed the influence of all types of prosthodontic treatments on patient satisfaction ratings and oral health related quality of life. They included a variety of studies designs and did not limit their research question to any specific treatment. Although their results show that edentate individuals benefit more from the use of implant-supported prostheses in the edentulous mandible, the authors suggest that implant prostheses should be provided with priority to those patients in whom conventional therapy has failed. Because of this recommendation, in this meta-analysis, we planned and carried out subgroup analyses of trials with participants who had major problems with their dentures. We expected that participants with high levels of impairment and who were referred for specialist care are not likely to be representative of a general population, both in terms of the size of the treatment effect

and in the level of treatment expectations.

Our meta-analysis revealed that, although the overall effect size was greater with mandibular implant overdentures, the magnitude of effect varied greatly among studies.

This heterogeneity should not be ignored. The meta-analysis shows that two studies of the six (Allen et al. 2006, Kapur et al. 1999) differed from the rest, because they found no differences between treatments in patient satisfaction ratings. Difference in patient characteristics (diabetic or maladaptive patients) could be one of the explanatory factors. Subgroup analyses restricted to trials with recruitment of individuals with severely impaired conditions indicated that the effect size increases (0.95), but statistical heterogeneity remains. The use of participants with high levels of impairment may increase the potential for selection bias in that population. However, several prospective and retrospective studies demonstrated that this group may show the greatest satisfaction or improvement in oral health related quality of life in view of their existing oral condition (Strassburger et al. 2006).

As with the oral health related quality of life, the overall effect size improved and heterogeneity disappeared only when those studies with participants from the general population, recruited via newspaper advertisements, were included. It should be noticed that two of these studies (Awad et al. 2000a, Awad et al. 2003b) were carried out in the same research center using almost identical protocols but different age groups. Therefore, this could explain why their results are so similar.

It is suggested that conclusions should not be drawn on the summary results when there are small numbers of trials available with many clinical differences. In such situations, ideas about the sources of heterogeneity could be considered as hypotheses for further studies (Thompson 1994). Therefore, we should be cautious about drawing

definitive conclusions and clinical practice guidelines from these results. However, they can be integrated with clinical judgements and expertise, patients' expectations and values as well as considerations of cost-effectiveness, for clinical decision making (Eddy, 2005).

This review confirms the results of Strassburger et al. (2006) that a limited number of studies, as well as a lack of sensitive and non generic instruments for measuring perceived general health, have hindered the transfer of knowledge in this field. Naito et al. (2006) has also addressed this issue in their review of the association between oral health status and health related quality of life. Thus, there is a need for adequately powered and properly designed clinical trials as well as more sensitive general health instruments to assess and compare the general and oral health quality of life of edentulous people wearing various types of prostheses.

In order to reduce the influence of chance effects in estimating treatment differences in meta-analyses, we support the use of individual patient data (IPD) or raw data (Clarke & Stewart 2001). We were impressed with the very supportive attitudes and offers of assistance when we contacted trialists involved in clinical implant research to request additional information about their trials. Therefore, we are planning a future meta-analysis using aggregate data from trialists. These IPD reviews are less prone to bias and can better ensure the quality of disseminated information.

Conclusions

The available evidence points to better patient based outcomes with mandibular implant overdentures. However, with regard to the magnitude of treatment effects, the results of this meta-analysis are inconclusive. We need additional meta-analyses on well conducted randomized controlled trials that include relevant economic assessments as a priori outcome to inform policy makers, insurers and the public in their decisions on adoption of implant therapies.

Implications for further research

As stated previously, there is a need for more well conducted randomized controlled trials to assess the real magnitude of effect of mandibular implant retained overdentures on patient satisfaction and oral health related quality of life. Furthermore, there is a need for further studies investigating the cost effectiveness of this technology.

Sensitive and appropriate general health and quality of life measures should be used in these studies. Some authors have advocated that mandibular implant overdentures should be provided only for patients with major problems with their conventional prostheses. Although the subgroup analysis in this trial indicates a positive impact of this treatment for the general population, it would be interesting to test this hypothesis in groups of patients whose conditions differ (e. g., those with severe resorption versus normal resorption, those with no problems with their conventional dentures versus those with severe problems) using a stratified randomisation strategy and a long term follow up period.

We emphasise the need for adequate reporting of results using the CONSORT guidelines (http://www.consort-statement.org/), as well as the inclusion of numbered

data to demonstrate treatment effects for facilitating and improve the quality of published meta-analyses.

Role of the Funding Source and potential conflict of interest

No external funding sources directly supported this meta-analytic study. One of the reviewers (E.E) is completing a PhD based on a randomized controlled trial in which this particular question is addressed. The corresponding author is the Principal Investigator on two of the included randomized controlled trials that were funded over the past 17 years by University/Industry grants from The Canadian Institutes of Health Research and Straumann Canada Ltd and by the Canadian Medical Research Council and Nobelpharma Canada, Inc. The corresponding author had full access to all data and final responsibility for the decision to submit this report for publication.

Acknowledgments

The authors are grateful to Dr Marie Hatem and Lisa McGovern for their generous assistance with the Revman software. We acknowledge Miguel Chagnon for helpful comments on statistical analysis and Monique Clar for her assistance on the search strategy. We also thank our research colleagues who responded so quickly to our email requests and provided us with supplementary information regarding their trials. Dr Emami is supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research.

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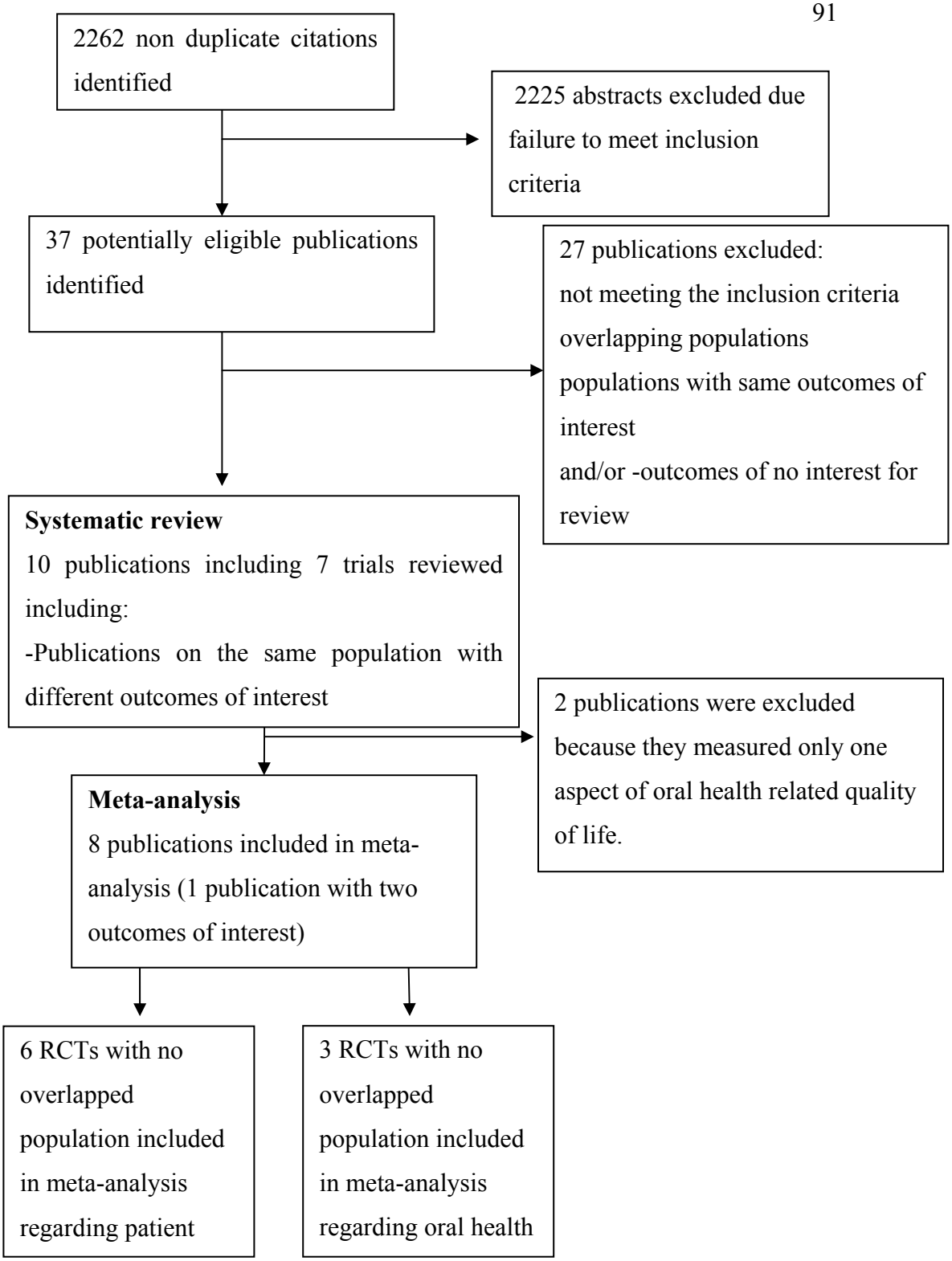

Figure 1: Flow chart of publication selection for inclusion in the systematic review and meta-analysis

Table 1: Summary of included manuscripts

Trial	First author	Location, date of study	Sample size	Age	Intervention Randomized number	*Outcomes*, instruments	Follow up Period and % drop out after randomization
1	Boerrigter (Boerrigter et al. 1995b)	The Netherlands, 1995	157	35-84	IOD* n=93 CD** n=64	*General satisfaction**** validated questionnaires	12 months; % 4
2	Bouma (Bouma et al. 1997)	The Netherlands, 1997	90	55±11	IOD* n=30 CD** n=30 PPS† n=30	*Psychological well being* GARS-D, Psycological Well Being Scale for denture patients, HSCL, LASA	12 months; % 4
3	Kapur (Kapur et al. 1999)	United States, 1999	102	48-75	IOD* n=40 CD** n=62	*General satisfaction**** validated questionnaires	6, 24 months; % 33, % 55
4	††Awad (Awad et al. 2000a) (Awad et al. 2003a)	Canada, 2000,2003	102	35-65	IOD* n=54 CD** n=48	*Oral health related quality of life*: OHIP 49; *General satisfaction**** validated questionnaires	2 months; % 4
	Heydecke	2005	102	35-65	IOD* n=54	*Social and sexual activities*	2 months;

	(Heydecke et al. 2005)				CD** n=48	SIQ questionnaire	% 4
5	††Awad (Awad et al. 2003b)	Canada, 2003	60	65-75	IOD* n=30 CD** n=30	*Oral health related quality of life* OHIP 20, OHIP 49, *General satisfaction* validated questionnaires	2 months; % 13
	Thomason (Thomason et al. 2003)		60	65-75	IOD* n=30 CD** n=30	*General satisfaction** validated questionnaires	6 months, % 20
6	Meijer (Meijer et al. 2003)	The Netherlands, 2003	121	IOD* 56.9±11.6 CD** 57.8±10.9	IOD* n=61 CD** n=60	*General satisfaction** validated questionnaires	1, 5, and 10 years; % 4, % 17, % 21
7	Allen (Allen et al. 2006)	United Kingdom, 2006	118	≤80	IOD* n=62 CD** n=56	*Oral health related quality of life* OHIP 49 *General satisfaction** validated questionnaires	3 months; 22%

IOD* Overdenture retained by implants CD** Conventional denture

*General satisfaction**** term used to explain Overall denture satisfaction

PPS† preprosthetic surgery and conventional denture

ARS-D Groningen Activity Restriction Scale-Dentistry

HSCL Hopkins Symptom Check List (HSCL)

LASA Linear Analogue Self-Assessment Method, one-Item version

†† Rows include trials with multiple publications reporting on different outcome

Table 1 (continued): Summary of included manuscripts

Trial	First author	Results
1	Boerrigter (Boerrigter et al. 1995b)	Better post-treatment scores for the IOD than the CD group for general satisfaction (P<0.001).
2	Bouma (Bouma et al. 1997)	Significant improvement in the average values of dental health related quality of life measures for both groups (P<0.001), except for the HSCL subscale on somatic complaints. Score of 0 before treatment for up to 43% of the analysed data. No within group difference for general quality of life measured by LASA. No significant differences between groups for all measures.
3	Kapur (Kapur et al. 1999)	No significant post treatment difference between group for patient satisfaction, although higher for the IOD group.
4	††Awad (Awad et al. 2000a) (Awad et al. 2003a)	Significant improvement from mean OHIP baseline to post-treatment scores for the IOD (P <0.05) in all subscales, including functional limitations, physical pain, psychological discomfort, physical disability, social disability and handicap. In contrast, pre-/post treatment improvements in the conventional group only for functional limitation and physical disability items. Significant mean post treatment scores between the groups for all 7 OHIP domains (P <0.05).
	Heydecke (Heydecke et al. 2005)	Less post treatment looseness in eating, speaking, yawning and kissing in IOD than CD (P<0.0001). Participants wearing implant overdentures had better sexual activity scores than did those in the conventional denture group. Moderate (r=0.5-0.7) correlation between total OHIP 49 scores and perceived prosthesis looseness.

		Weak correlation for social and sexual activity and for total OHIP 49 scores.
5	††Awad (Awad et al. 2003b)	Significant between-group difference only in the physical pain domain for OHIP-49. Significant differences between the two groups for total score, functional limitations, physical pain and physical disability with the OHIP 20. CD group: Pre/post treatment differences using the OHIP-49 for the total score, functional limitation and physical disability. IOD group: Significant pre/post treatment differences with the OHIP 20 in all domains, including total score and in all domains except psychological disability using the OHIP-49.
	Thomason (Thomason et al. 2003)	Significant post-treatment difference between group in general satisfaction (P=0.005). Significant pre-post treatment difference for both groups (P <0.001). Magnitude of change greater for IOD group (22.4 mm mean difference).
6	Meijer (Meijer et al. 2003)	Significant difference between group (P=0.001) according to patient satisfaction at 1, 5 and 10 years follow up. Mean satisfaction score of CD group (including 40% who later received implants) lower than IOD.
7	Allen (Allen et al. 2006)	Comparable post-treatment OHIP means in both groups. Both groups showed significant improvements in OHIP scores from baseline to 3 months after treatment (P <0.001). The ES of the change in the OHIP score was 1.1 for the IOD group and 1.0 for the CD group. The pre-/post treatment change scores significantly higher for the IOD receivers than for those who refused IOD and

		received CD (P <0.001).

IOD* Overdenture retained by implants CD** Conventional denture

*General satisfaction**** term used to explain Overall denture satisfaction

PPS† preprosthetic surgery and conventional denture

ARS-D Groningen Activity Restriction Scale-Dentistry

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†† Rows include trials with multiple publications reporting on different outcome

Table 2. Methodological quality summary: review authors' judgments about each methodological quality item for each included study.

Trial	Adequate Sequence generation	Allocation concealment	Report on withdrawals and drop out
Boerrigter (Boerrigter et al. 1995b)	+	?	+
Bouma (Bouma et al. 1997)	+	?	+
Kapur (Kapur et al. 1999)	+	?	+
†Awad (Awad et al. 2000a) (Awad et al. 2003a) Heydecke (Heydecke et al. 2005)	+ +	? ?	+ +
†Awad (Awad et al. 2003b) Thomason (Thomason et al. 2003)	+ +	? ?	+ +
Meijer (Meijer et al. 2003)	+	?	+
Allen (Allen et al. 2006)	+	?	+

+Adequate ? not reported — Inadequate

† Rows include trials with multiple publications reporting on different outcomes

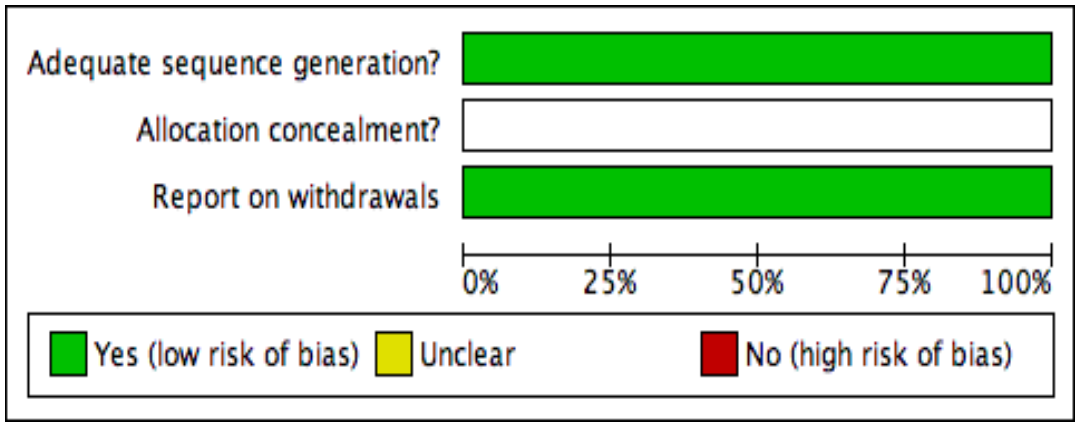

Figure 2: **Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies**

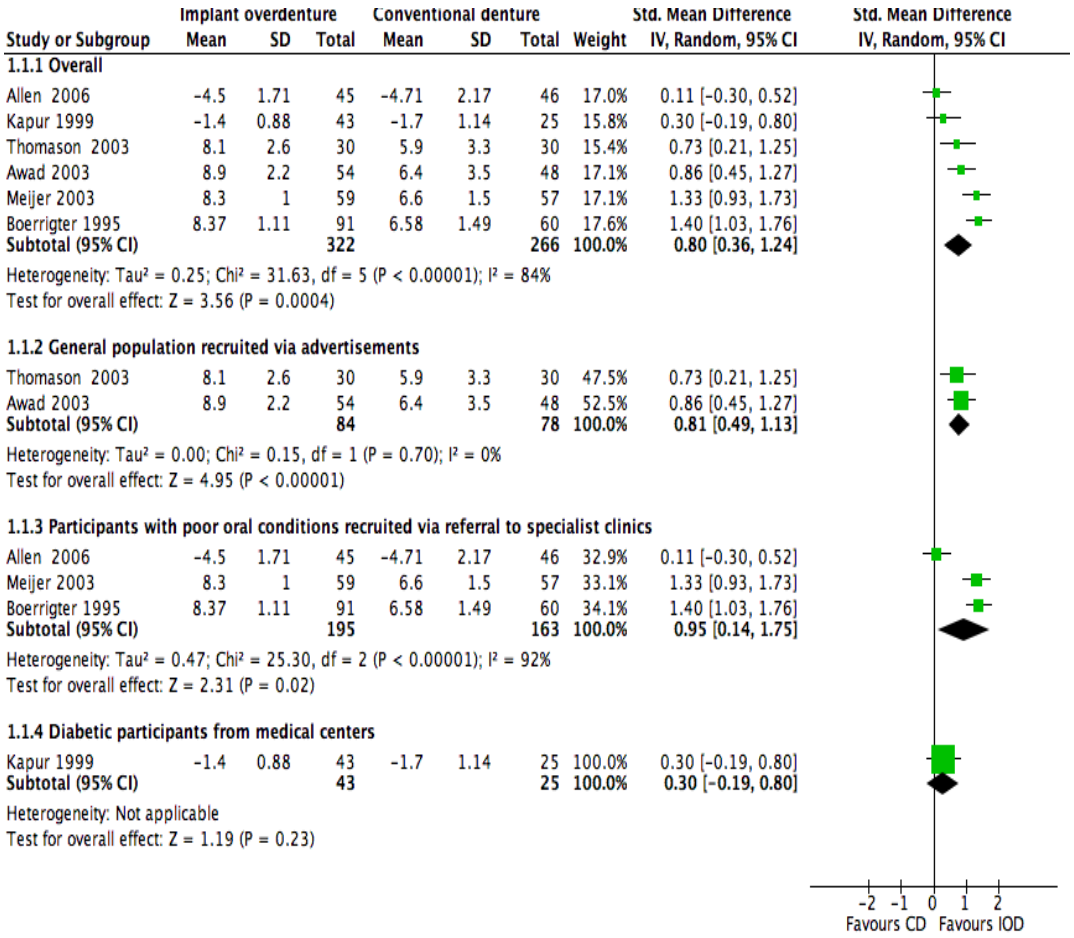

Figure 3: Meta analysis of randomized trials comparing mandibular implant overdentures with conventional dentures on patient rating of satisfaction

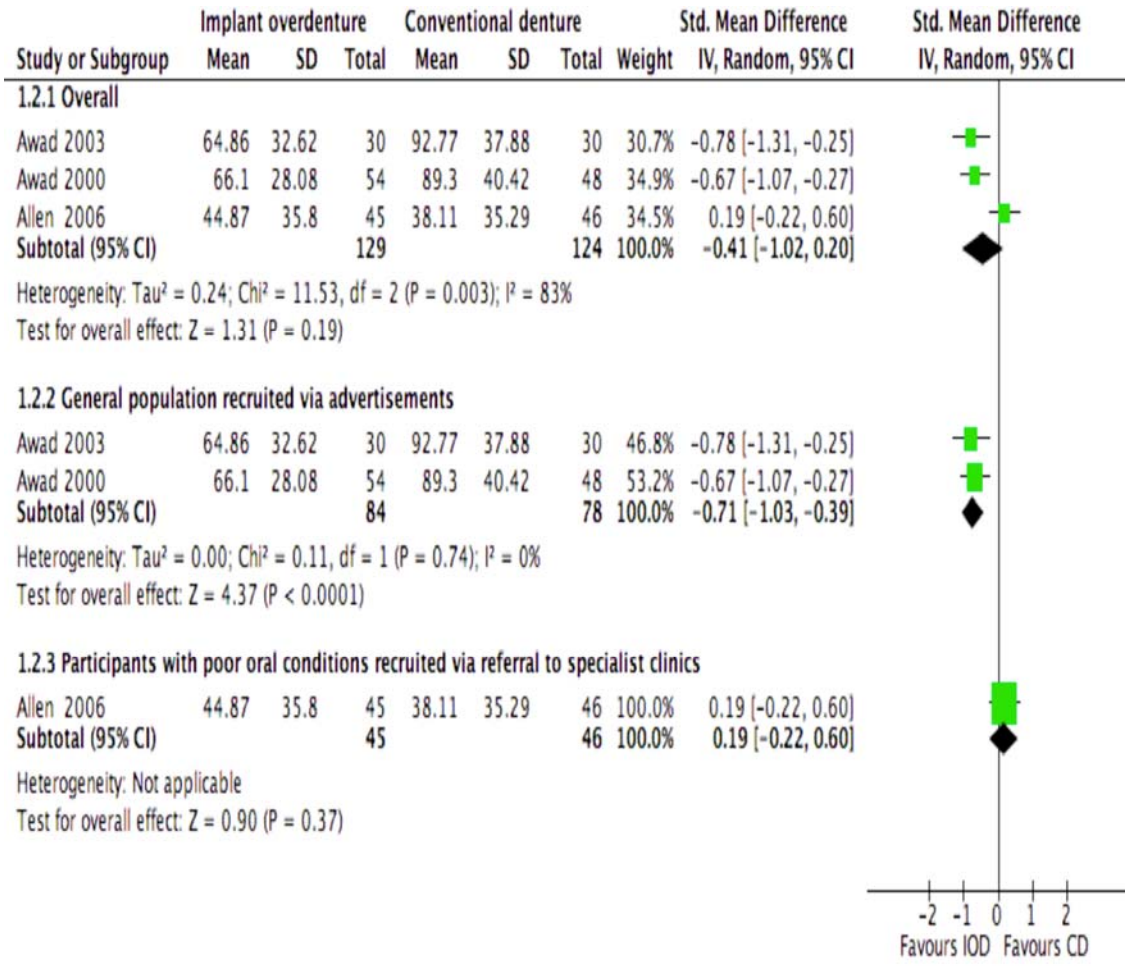

Figure 4: Meta analysis of randomized trials comparing mandibular implant overdentures with conventional dentures on oral health related quality of life

Appendix 1 : Search strategy developed for Medline (via PubMed) and revised appropriately for each search database

Search :#1

(denture) OR (complete denture) OR (complete lower dental prosthesis) OR (dental prosthesis) OR (implant supported) OR (implant overdenture) OR (overdenture) OR (dental implantation) OR (dental implant)

Query Translation

denture	"dentures"[MeSH Terms] OR "dentures"[All Fields] OR "denture"[All Fields]
complete denture	"denture, complete"[MeSH Terms] OR ("denture"[All Fields] AND "complete"[All Fields]) OR "complete denture"[All Fields] OR ("complete"[All Fields] AND "denture"[All Fields])
Complete lower dental prosthesis	complete [All Fields] AND lower[All Fields] AND ("dental prosthesis"[MeSH Terms] OR ("dental"[All Fields] AND "prosthesis"[All Fields]) OR "dental prosthesis"[All Fields]))
dental prosthesis	"dental prosthesis"[MeSH Terms] OR ("dental"[All Fields] AND "prosthesis"[All Fields]) OR "dental prosthesis"[All Fields]
Implant supported	implant[All Fields] AND supported[All Fields]
Implant overdenture	implant[All Fields] AND ("denture, overlay"[MeSH Terms] OR ("denture"[All Fields] AND "overlay"[All Fields]) OR "overlay denture"[All Fields] OR "overdenture"[All Fields]))
overdenture	"denture, overlay"[MeSH Terms] OR ("denture"[All Fields] AND "overlay"[All Fields]) OR "overlay denture"[All Fields] OR "overdenture"[All Fields]
dental implantation	"dental implantation"[MeSH Terms] OR ("dental"[All Fields] AND "implantation"[All Fields]) OR "dental implantation"[All Fields]
dental implant	"dental implants"[MeSH Terms] OR ("dental"[All Fields] AND "implants"[All Fields]) OR "dental implants"[All Fields] OR ("dental"[All Fields] AND

	"implant"[All Fields]) OR "dental implant"[All Fields]

Search**:** #2

(health) OR (general health) OR (oral health) OR (patient satisfaction) OR (quality of life)) OR (outcome assessment) OR (outcome and process assessment) OR (treatment outcome) OR (health status) OR (health status indicator)) OR (public health) OR (mental health) OR (oral hygiene)) OR (SF-36) OR (OHIP) OR (physical activity scale)

Query Translation

health	"health"[MeSH Terms] OR "health"[All Fields]
General health	"general"[All Fields] AND ("health"[MeSH Terms] OR "health"[All Fields])
oral health	"oral health"[MeSH Terms] OR ("oral"[All Fields] AND "health"[All Fields]) OR "oral health"[All Fields]
patient satisfaction	"patient satisfaction"[MeSH Terms] OR ("patient"[All Fields] AND "satisfaction"[All Fields]) OR "patient satisfaction"[All Fields]
quality of life	"quality of life"[MeSH Terms] OR ("quality"[All Fields] AND "life"[All Fields]) OR "quality of life"[All Fields]
outcome assessment	"outcome assessment (health care)"[MeSH Terms] OR ("outcome"[All Fields] AND "assessment"[All Fields] AND "(health"[All Fields] AND "care)"[All Fields]) OR "outcome assessment (health care)"[All Fields] OR ("outcome"[All Fields] AND "assessment"[All Fields]) OR "outcome assessment"[All Fields]
outcome and process assessment	"outcome and process assessment (health care)"[MeSH Terms] OR ("outcome"[All Fields] AND "process"[All Fields] AND "assessment"[All Fields] AND "(health"[All Fields] AND "care)"[All Fields]) OR "outcome and process assessment (health care)"[All Fields] OR ("outcome"[All Fields] AND "process"[All Fields] AND "assessment"[All Fields]) OR "outcome and process assessment"[All Fields]
treatment outcome	"treatment outcome"[MeSH Terms] OR ("treatment"[All Fields] AND "outcome"[All Fields]) OR "treatment outcome"[All Fields]
health status	"health status"[MeSH Terms] OR ("health"[All Fields] AND "status"[All Fields]) OR "health status"[All Fields]
health status indicator	"health status indicators"[MeSH Terms] OR ("health"[All Fields] AND "status"[All Fields] AND "indicators"[All Fields]) OR "health status indicators"[All Fields] OR ("health"[All Fields] AND "status"[All Fields] AND "indicator"[All Fields]) OR "health status indicator"[All Fields]
public health	"public health"[MeSH Terms] OR ("public"[All Fields] AND "health"[All Fields]) OR "public health"[All Fields]
mental health	"mental health"[MeSH Terms] OR ("mental"[All Fields] AND "health"[All Fields]) OR "mental health"[All Fields]
oral hygiene	"oral hygiene"[MeSH Terms] OR ("oral"[All Fields] AND "hygiene"[All Fields]) OR "oral hygiene"[All Fields]
SF-36	SF-36[All Fields])
OHIP	OHIP[All Fields])
Physical activity scale	("motor activity"[MeSH Terms] OR ("motor"[All Fields] AND "activity"[All Fields]) OR "motor activity"[All Fields] OR ("physical"[All Fields] AND "activity"[All Fields]) OR "physical activity"[All Fields]) AND ("weights and measures"[MeSH Terms] OR ("weights"[All Fields] AND "measures"[All Fields]) OR "weights and measures"[All Fields] OR "scale"[All Fields]))

Search #3: **(#1) AND (#2)**

The above search was run with Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); PubMed format

1. randomized controlled trial [pt]

2.controlled clinical trial [pt]

3.randomized [tiab]

4.placebo [tiab]

5.clinical trials as topic [mesh: noexp]

6.randomly [tiab]

7.trial [ti]

8.#1 or #2 or #3 or #4 or #5 or #6 or #7

9. humans [mh]

10. #8 and #9

3.3 MANUSCRIPT # 3

Oral and general health quality of life for edentulous elders wearing two-implant overdentures: results from a one-year randomized trial

Accepted for presentation at International Association for Dental Research (IADR) 87th General Session & Exhibition

In preparation

Oral and general health quality of life for edentulous elders wearing two-implant overdentures: results from a one-year randomized trial.

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Abstract

There is still insufficient information as to whether implant treatment can assist in maintaining perceived oral and general health in edentulous elders on the long term. This randomized clinical trial aims to compare the effects of mandibular two-implant overdentures and conventional dentures on oral health related quality of life (OHRQoL) and perceived general health at a one year follow-up.

Methods: Two hundred fifty five men and women (mean age 70.0 ± 4.8) had randomly received mandibular two-implant retained overdentures (IOD) or conventional dentures (CD), both opposed by new conventional maxillary dentures. The outcome variables, oral health related quality of life and perceived general health were measured with the Oral Health Impact Profile (OHIP-20) and the Short Form 36 (SF-36) at baseline and at one year following treatment. Between-group comparisons were performed using independent samples *t*-tests for continuous variables and Chi-square tests for categorical variables. Within-group comparisons were assessed using paired samples *t*-tests. Regression models were applied to measure the extent to which the explanatory variables predict OHIP and Physical Component Summary scores (PCS) of the SF-36.

Results: Pre/post treatment differences in total OHIP scores were significantly greater for the IOD than the CD group ($p \leq 0.05$). Type of treatment (beta = -0.26 $p < 0.001$) and pretreatment scores (beta = 0.27 $p < 0.001$) were significant contributors to oral health related quality of life. There were no between-group differences found in SF-36 subscale scores. The conventional denture group had a statistically

significant decrease in PCS, physical functioning, role physical and bodily pain from baseline to the one-year follow-up, indicating decreased perceived general health. In the implant overdenture group, no statistically significant decrease was seen in S-36 subscales scores from baseline to the one year follow-up, except for bodily pain. The final regression model demonstrated that, after controlling for age, sex, marital status and type of treatment, OHIP total final scores (beta = -0.27 $p<0.001$) and PCS baseline scores (beta = 0.44 $p<0.001$) predict PCS summary final scores.

Conclusions: The results of this study suggest that, in edentulous elders, mandibular two-implant retained overdentures provide significant long term improvement in oral health related quality of life. Oral health related quality of life is a significant predictor of perceived physical health. Therefore, edentulous elders may encounter barriers to physical health if the level of their oral health quality of life is low.

Key words: oral health related quality of life, clinical trial, perceived general health, implant overdenture, SF-36, OHIP

Introduction

The globe is graying, with the majority of older people living longer than previous generations. Thus, health care services face many new challenges (1). In order to postpone gradual limitations in function and to maintain quality of life for elders, health care providers need to promote preventive interventions and assure high quality health care (2, 3). This is especially important for edentulous elders, for whom a complete cure of their condition, edentulism, is not possible. Therefore, it is essential for clinicians to understand the factors that will keep elders healthy and improve the quality of their lives. Measurement of perceived general health and quality of life can assist in the determination of those at risk for poor health and serve as part of the diagnostic and therapeutic process. Over the last decades, convincing evidence has accumulated linking improved oral health related quality of life and satisfaction of edentulous elders to the beneficial effects of implant retained dentures (4-9). However, the results of our recent meta-analysis and systematic review of the impact of implant retained dentures on oral and general health related quality of life shows that there is still a major gap in the evidence (10). Only 3 randomized controlled trials (RCT) tested whether implant overdenture therapy can improve oral health related quality of life (5, 7, 11) and one assessed their impact of mandibular implant overdenture on perceived general health (12) with a maximum of 6 months follow up. As a result, there is insufficient information as to whether implant treatment can assist in maintaining or increasing perceived oral or general health in edentulous elders on the long term.

This randomized clinical trial aims to compare the effects of mandibular two-implant overdentures and conventional dentures on the oral health related quality of life

(OHRQoL) and perceived general health of edentulous elders one year following prosthesis delivery. We hypothese that:

-mandibular two-implant overdenture wearers rate their oral health related quality of life better than those wearing conventional dentures;

-elders wearing mandibular two-implant overdentures rate their general health better than those wearing conventional dentures.

Material and Methods

Study population

This article reports on the results of secondary outcomes at a one year follow up of a randomized controlled study designed to evaluate whether two-implant mandibular overdentures can improve nutrition significantly more than conventional dentures in edentulous elders.

Newspaper advertisements in Montreal, Canada were used to recruit healthy men and women 65 years or older, wishing to replace their existing conventional dentures with new dentures. Details of the recruiting process, as well as inclusion and exclusion criteria for this randomized controlled trial have been described previously (13-15).

Respondents were interviewed by telephone to determine eligibility. Interested participants (n=703) attended an information session, followed by screening evaluations that included medical history and clinical and medical examinations to assure inclusion criteria eligibility. Two hundred and fifty-five participants were enrolled in this study. The study received approval from McGill University's Institutional Review Board, and all participants provided their written informed consent to participate in this study.

Randomization, intervention procedures and assessment

Following baseline assessments, study participants were randomly assigned to the treatment group using a central computer-generated random permutation procedure. The study personnel who maintained the randomization log were not involved in patient contact, treatment or data gathering. Participants randomly received either mandibular conventional dentures or overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland), both opposed by new conventional maxillary dentures. Published standard surgical and prosthodontic procedures were followed (5-7). Individuals enrolled in the study underwent a series of assessments at baseline and after delivery of the prostheses at 6 and 12 months. The 12-month follow up was carried out in 2 parts, one for physiologic and clinical outcomes and the other for patient-based outcomes.

Prior to the baseline assessments, the participants received instructions on how to complete each questionnaire. In this study, blinding of participants and care providers to intervention was not possible due to the nature of implant therapy. However, those who entered and analyzed the data were blind to treatment allocation.

Outcomes and measurement instruments

Patient-based outcomes in this study were: oral health related quality of life and perceived general health.

Oral health related quality of life was assessed using the Oral Health Impact Profile (OHIP-20) (5). The Oral Health Impact Profile (OHIP-20) is a validated disease–specific measure of edentulous people's perceptions of the physical, psychological and social impacts of their oral health on their well-being. This 20-item questionnaire includes 7 domains: functional limitation, physical pain, psychological discomfort,

physical disability, psychological disability, social disability and handicap (16-18). The total range of the scale is 20-120 points, with lower scores indicating better oral health-related quality of life.

Change in perceived general health was assessed using the Short Form-36 (SF-36) (19). The SF- 36 is a generic self-administered questionnaire consisting of 8 multi-item subscales: physical functioning, social functioning, role limitations due to physical health problems, role limitations due to personal or emotional problems, mental health, vitality, pain and general health perceptions. To facilitate discussion of the results, the scores of these subscales are combined into two summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). PCS emphasizes the physical function, role physical, bodily pain and general health perceptions and the MCS focuses on the vitality, social functioning, role emotional and mental health scores. The SF-36 has excellent internal consistency and can discriminate between individuals with and without chronic diseases (19-26). The computerized scoring system used in this study was conducted according to the user's manual (20). Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 represent a better condition.

Statistical Analysis

According to the literature, for a treatment difference of 20 OHIP points, at a level of significance of p=0.05 with 80% power, a minimum of 86 participants is needed (5). Thus, even with an expected dropout rate of 20%, this study was sufficiently powered to assess OHIP-20 ratings according to treatment received.

All data were entered and submitted to a third-party data management company. The accuracy of data entries was verified and certified for submission by independent research assistants. The investigators who carried out the data analyses were blind to treatment assignment. All analyses were conducted using the SPSS 16.0 statistical software package.

Comparisons of continuous variables between groups were performed with independent samples *t*- tests as well as chi-square tests for categorical data. Paired *t*-tests were used to compare the baseline and one year follow-up scores. Effect sizes (ES) were calculated to evaluate the magnitude of change from pre to post treatment (27). Effect sizes of <0.5, $0.5<ES<0.8$ and >0.8 are classified as small, moderate and large, respectively. Linear multiple regression analyses were used to assess the association between the outcome variables and treatment assignment, after adjusting for the effect of independent variables.

We have carried out intention to treat analyses, as well as completer analyses which did not include dropouts to assess their influence on outcome. We used individual pre-treatment scores for the imputation procedure (28).

Results

Participant Characteristics

The mean age of the sample was 70.0 ± 4.8 years, with 55.3% female and 51.4% married. A minority of participants (8.6%) were employed. The education of the majority was below college level (62%), and their income was less than 40.000 $ CAD (78.4%). There were no significant differences in the participant's baseline characteristics (socio-demographic factors and study outcomes) according to treatment allocation (Table 1).

A total of 219 (CD n = 109, IOD n = 110) study participants returned for the one year follow-up (Figure 1). From the initial 255 study participants, 16 dropped out after randomization, 9 dropped out at six months and 11 dropped out at the one year follow up (Figure 1). Reasons for the dropouts were medical problems unrelated to study participation, personal reasons unrelated to study participation (moved away, not interested, death), fear of implant surgery and loss of contact. The baseline characteristics of the participants who dropped out and those who did not are shown in Table 1. There were no significant differences between these two groups, except for marital status. In the drop-out group, the number of married individuals was less than in the completer group (p=0.005, Pearson Chi-Square).

Treatment outcomes

Oral health related quality of life

The results of both analytic approaches (intention to treat and the completer analyses) were similar (Table 3). Compared to baseline, both groups reported substantial improvement in oral health quality of life at the one-year follow up. Within group improvement was statistically significant on all OHIP subscales for both groups ($p \leq 0.001$). However, there were significant between differences group post-treatment ($p \leq 0.05$). Significantly lower scores in all OHIP domains were observed for the IOD group (Table 3). Pre/post treatment change scores were significantly greater for the IOD group than the CD group ($p \leq 0.05$). The effect size (magnitude of change) was larger (1.1 versus 0.7) for the IOD group than the CD group.

Hierarchical multiple regression was used to assess whether type of treatment and OHIP total baseline scores predict levels of the final total OHIP scores after controlling for the influence of age, sex and marital status. Preliminary analysis ensured no violation of assumptions of normality, linearity and multicollinearity. Age, sex and marital status were entered at Step 1, explaining 2% of the variance in perceived oral health quality of life. After entry of the OHIP baseline score and type of treatment at Step 2, the two variables explained an additional 14% of the variance in OHIP post-treatment total scores, after controlling for age, sex and marital status (R square change 0.143, F change (2.212)=18.121 $p<0.001$). In the final model, only OHIP baseline scores (beta = 0.27, $p<0.001$) and type of treatment (beta = -0.26, $p<0.001$) were statistically significant predictors of oral health related quality of life (Table 4).

Perceived general health

In this sample of edentulous elders at the one year follow up, the mean PCS and MSC scores were 49.4±9.8 (age adjusted Canadian Normative data 47.2 ±9.7) and 53.81 ± 8.6 (age adjusted Canadian Normative data 53.7±8.3), respectively. There was a sex difference within the sample population, with men scoring higher than women for all SF-36 domains. This difference was significant at baseline on mental health (*t*-tests p=0.04, 95% CI -8.2, -0.1). Furthermore, at the one year follow up, men scored significantly higher than women for physical functioning, role physical, mental health, vitality and bodily pain (*t*-tests p=p≤0.05) as well as on the Physical Component Summary(*t*-tests p=0.01, 95% CI -5.9, -0.8).

At baseline and at the one year follow up, no differences between group were observed in any of the SF-36 domains or summary scores (Table 5). A paired samples t–test was conducted to evaluate the impact of the intervention on SF-36 domains and summary scores from baseline to follow up. In the conventional denture group, there was a statistically significant decrease in the PCS, physical functioning, role physical and bodily pain from baseline to the one year follow up (Table 5). In the implant retained overdenture group, no statistically significant decrease was seen from baseline to the one year follow up, except for bodily pain (paired difference mean 4.6, SD 22.8, 95% CI 0.2 -8.9, t=2.07, p=0.04). Furthermore, the size of the pre/post treatment decrease in the CD group for PCS in the CD group (-3.5 points) was clinically important, while the decrease in the IOD group (-1.2 points) was not (29).

Table 6 presents the final regression model of 12 month post treatment Physical Component Score (PCS). After controlling for age, sex, marital status and type of treatment, only gender, the OHIP total final scores and PCS baseline scores predict the PCS final scores. In addition, these variables explained 29% of the variation in the PCS post treatment scores.

Discussion

The main purpose of this study was to evaluate the efficacy of mandibular two-implant overdentures in improving oral health quality of life and perceived general health of edentate elders after one year of wearing prostheses. We found that participants, who wore mandibular two-implant overdentures for one year, had higher oral health related quality of life compared to those who wore new conventional dentures. Our results also demonstrated that perceived general health, regardless of type of treatment, is decreased after one year of follow up. Surprisingly, the decrease in scores related to physical factors was statistically significant only for those who wore conventional dentures.

To the best of our knowledge, this is the first randomized controlled trial to compare the impact of mandibular two-implant retained overdentures on oral and general health related quality of life after a one-year follow up. We found only 3 RCTs, in which the oral-health-related quality of life of subjects wearing mandibular two-implant overdentures or conventional dentures, was compared (5, 7, 11). In all of these trials, the outcome was assessed at 6 months or less. However, the evolution of quality of life following an intervention is essential, because any measure of change may be influenced by several factors as a result of the passing of time. Our findings

confirm the results of our previous RCTs (2 of the 3 RCTs), indicating that mandibular two- implant overdenture wearers have better oral health quality of life than those wearing conventional dentures (5, 7, 11). In addition, our results demonstrate that the difference in improvement or magnitude of change is maintained over a one year follow up period.

The third randomized controlled trial in this field was carried out by Allen et al (11). In that study, the authors found no significant differences in quality of life of participants who wore mandibular implant overdentures or conventional dentures. The authors suggested that implant treatment effects may be masked by application of "intention to treat" analysis. An intention to treat analysis is often preferred to a completer analysis, since ignoring dropouts often leads to biased inferences. We carried out both complete and intention to treat analyses to explore any potential effect of type of analysis. Our results support the body of evidence that intention to treat analysis does not affect the results of treatment effects. Therefore, we suggest that this difference in findings may be due firstly to differences in patient recruitment, patient characteristics, duration of follow up and the extent of withdrawals. Secondly, the handling of an intention to treat analysis could influence the results. Furthermore, we emphasize that a treatment difference that is meaningful to a patient may not be statistically significant. In our study, the magnitude of change in oral health related quality of life was 1.5 times higher for those in the implant group that in the conventional denture group (Table 3). Furthermore, an effect size of more than 1 is large enough to be clinically meaningful as defined by Cohen (27). It is important to interpret quality of life outcomes in clinically useful ways, since more and more, oral health related quality of life is chosen as study outcome.

Our results indicate that, regardless of type of treatment, perceived general health measured with the SF-36 is decreased after one year of follow up. Furthermore, women have lower scores than men for all SF-36 domains. A decrease in perceived general health over the time is expected, given the influence of factors such as aging (30). The sex differences found in perceived general health have also been well documented in the literature (30). On one hand, it was interesting to see that the decrease in scores related to physical factors was statistically significant only for those who wore conventional dentures. However, on the other hand, results of our regression analysis, confirmed that oral health related quality of life is a significant predictor of perceived physical health status. Maintaining quality of life and function is a primary goal of health care interventions. The statistically and clinically significant decrease in physical functioning, role physical and physical component summary scores in the conventional, and not in the implant group, suggests that implant overdentures could contribute to maintain perceived general physical function. Evidence from the literature supports this hypothesis. Akifusa et al. (31) used the SF-36 to measure the physical health of 207 Japanese elders. They demonstrated that oral conditions (number of teeth) were significantly related to the physical health of elders. Shimazaki et al. (32) carried out a six-year prospective cohort study of the institutionalized elders. They found that the perceived physical ability of edentulous individuals without denture was significantly lower and their mortality rate was significantly higher than dentate individuals. However, only one randomized controlled trial has tested the effect of mandibular implant overdentures on general health (12). Consistent with their findings, we found no differences between group regarding perceived general health. However, this does not exclude a possible difference for two main reasons: instrument sensitivity and sample size. It is

reported that site-specific instruments, such as the OHIP, will be more sensitive than generic health instruments (33) to detect differences in oral treatment outcomes. We used the generic instrument, SF-36, to measure perceived health because the literature recommends using both a generic and a specific instrument to measure quality of life amongst people with chronic conditions such as edentulism (34). However, when instruments are less sensitive, the sample sizes must be greater in order to detect intervention differences (35). We consider the lack of findings of post treatment differences on perceived general health are likely due to a sample size that is too small (35), because the sample size targeted for this trial was calculated for the primary outcomes. Further research with an adequate sample size would be necessary to explore the effect of type of treatment on perceived general health. We should also carry out additional studies using appropriate research designs to evaluate the possible pathways contributing to this potential effect.

Selection bias could influence the results of this study because only edentulous elders with sufficient cognitive and physical capabilities were accepted to participate in this study. Therfore, our results do not generalize to population of elders that include those who are homebound, ill or cognitively impaired.

In conclusion, the results of this study extend and broaden the evidence supporting the efficacy of mandibular two-implant overdentures for enhancing oral health related quality of life in elders.

Our findings suggest that edentulous elders may encounter barriers to physical health because of the level of their oral health quality of life.

Aknowledgment

This study was funded by CIHR Industry Grant # UCR-36052 with Straumann Canada Limited and by the ITI foundation. Dr Emami is supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research.

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Figure 1: Study flow chart

Table 1: Demographic variables and baseline outcome scores according to treatment allocation

Variables	**IOD (n 127)**	**CD (n 128)**	**p value**
Age (mean±SD)	70.4±5.0	69.6±4.5	0.2
Gender			
Males	57	57	0.9
Females	70	71	
Marital status			
Married/couple	68	53	0.1
Single/divorced/widow	58	73	
No answer	1	2	
Education			
Below college level	81	77	
College level or higher	46	47	0.1
No answer	0	4	
Income			
< 40000	97	103	
³ 40000	24	19	0.7
No answer	6	6	
OHIP (mean±SD)	54.3±20.2	56.4±20.4	0.4
SF 36			
MCS (mean±SD)	54.0±8.5	53.0±9.6	0.4
PCS (mean±SD)	51.3±8.0	52.2±7.8	0.4

Table 2: Demographic variables and baseline outcome scores between dropouts and completers

Variables	Completers (n=219)	Dropouts (n=36)	p value
Age (mean±SD)	69.8±4.7	71.2±5.4	0.09
Gender			
Males	100	14	0.2
Females	119	22	
Marital status			
Married	95	26	
Single/divorced/widow	121	10	0.005
No answer	3	0	
Education			
Below college level	136	22	
College level or higher	79	14	0.6
No answer	4	0	
Income			
<40000	168	32	
≥40000	41	2	0.1
No answer	10	2	
Treatmeant allocation			
Implant overdenture	110	17	0.4
Conventional denture	109	19	
OHIP (mean± SD)	55.4±20.5	55.2±19.6	0.9
SF 36			
MCS (mean±SD)	53.5±8.7	53.6±10.9	0.9
PCS (mean±SD)	51.8±8.1	51.2±6.7	0.6

Table 3: Between and within group comparisons of OHIP-20 scores

OHIP scores	Implant overdenture		Conventional denture		Effect size	
	Pretreatment Mean (SD)	One year Mean (SD)	Pretreatment Mean (SD)	One year Mean (SD)	IOD	CD
Functional limitation	11.4±3.7	6.4±3.2 [a,b]	11.7±3.8	7.8±3.8 [a]	1.4	1.0
Physical pain	12.5±4.9	6.6±3.8 [a,b,c]	13.4±5.3	9.6±5.0 [a]	1.2	0.7
Psychological discomfort	6.1±2.9	3.0±1.6 [a,b,c]	6.2±3.0	4.1±2.6 [a]	1.1	0.7
Physical disability	10.4±5.0	5.6±3.1 [a,b,c]	11.2±5.3	7.4±4.4 [a]	1.0	0.7
Psychological disability	5.6±2.4	2.9±1.8 [a,b]	5.6±2.7	3.9±2.2 [a]	1.1	0.6
Social disability	4.6±2.7	3.2±0.9 [a,b]	4.5±2.7	3.7±2.2 [a]	0.5	0.3
Handicap	4.0±2.4	2.3±1.0 [a,b]	3.8±2.4	2.7±1.6 [a]	0.7	0.5
Total OHIP						
Completer (n=219)	54.3±20.2	30.0±13.6 [a,b,c]	56.4±20.5	39.2±19.5 [a]	1.2	0.8
Intent to treat (n=255)	54.3±20.2	32.8±15.8 [a,b,c]	56.4±20.5	42.2±20.9 [a]	1.1	0.7

[a] Significant difference within each treatment groups, paired *t*-tests ($p \leq 0.001$)

[b] Significant difference between groups; Independent *t*-tests ($p \leq 0.05$)

[c] Significant difference between groups; Independent *t*-test ($p \leq 0.0001$)

Table 4: Regression model of 12 month post treatment OHIP-20 total scores, adjusted for pretreatment scores, age, gender and marital status

	Unstandardized Coefficients		Standardized Coefficients			95% Confidence Interval for B	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
age	0.194	0.240	0.051	0.807	0.421	-0.280	0.668
Gender [a] Females	1.503	2.418	0.043	0.622	0.535	-3.264	6.270
Marital status [b] Married/couple	-2.037	2.420	-0.058	-0.842	0.401	-6.807	2.733
Prosthesis type [c] implant - overdenture	-9.394	2.230	-0.270	-4.212	0.000	-13.790	-4.998
Total OHIP-20 score at baseline	0.229	0.055	0.270	4.171	0.000	0.121	0.337

[a] Males

[b] Single/ divorced/widow

[c] Conventional denture

Table 5: Between and within group comparisons of SF-36 scores

	Implant overdenture		**Conventional denture**	
SF-36 Sub-scales	Base line ±SD	One year ±SD	Base line ±SD	One year ±SD
Physical functioning	80.3±20.8	77.4±23.0	81.7±18.8	75.6±25.2*
Role physical	86.3±29.8	78.6±35.1	85.0±30.1	77.1±37.3*
Bodily pain	78.3±24.2	74.2±15.7*	78.4±21.9	71.2±25.6*
General health	78.7±18.8	79.5±15.01	79.0±17.6	77.3±17.0
Vitality	74.2±15.7	71.0±16.5	72.5±17.6	70.1±16.4
Social functioning	88.7±19.4	86.7±21.3	89.0±17.4	85.7±20.3
Role emotional	90.2±25.9	85.1±31.1	87.0±28.3	85.9±30.2
Mental health	79.8±16.3	79.2±16.9	78.2±17.5	79.4±14.0
Physical component	51.3±8.0	50.1±8.8	52.2±7.8	48.8±10.8**
Mental component	54.0±8.5	53.6±9.7	53.0±9.6	54.0±7.6

*Paired differences, Sig (2-tailed) $p<0.05$

** Paired differences, Sig (2-tailed) $p<0.0001$

Table 6: Regression model of 12 month post treatment Physical Component Score (PCS)

	Unstandardized Coefficients		Standardized Coefficients			95% Confidence Interval for B	
Variables*	**B**	**Std. Error**	**Beta**	**t**	**Sig**	**Lower Bound**	**Upper Bound**
Gender [a] Female	-2.571	1.214	-0.131	-2.119	0.035	-4.963	-0.179
PCS Baseline score	0.542	0.069	0.446	7.799	0.000	0.405	0.679
OHIP-20 Final total score	-0.157	0.034	-0.278	-4.667	0.000	-0.223	-0.091

Non significant variables (age, marital status and type of intervention) not showed in table.

[a] Males

3.4 MANUSCRIPT # 4

Favoring trauma as an etiological factor in denture stomatitis.

J Dent Res. 2008 May; 87(5):440-4.

Preliminary report was presented at International Association for Dental Research (IADR) 85th General Session & Exhibition

Favoring Trauma as an Etiological Factor in Denture Stomatitis

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Key Words: implant overdentures, dental prostheses, denture stomatitis, randomized cross sectional study, oral health.

ABSTRACT

The etiology of denture stomatitis remains controversial. Trauma due to unstable dentures has been suggested as an etiological factor. Therefore, we tested the hypothesis that the prevalence of denture stomatitis is reduced when mandibular dentures are stabilized by implants.

Data were collected at a one-year follow-up from 173 edentulous elders who had randomly received mandibular implant overdentures or conventional dentures. The diagnosis of denture stomatitis was determined according to the Newton classification. Elders wearing conventional dentures were almost 5 times more likely to have denture stomatitis than those wearing mandibular two-implant overdentures ($P < 0.0001$, Fisher's exact test). Adjusted odds ratios showed that only the type of the prosthesis (AOR=4.54, 95% CI 2.20 to 9.40) and nocturnal wear (AOR=3.03, 95% CI 1.24 to 7.40) predict the frequency of denture stomatitis. Thus, implant overdentures may reduce oral mucosa trauma and control denture stomatitis.

INTRODUCTION

There is growing interest in identifying the pathological determinants of conditions affecting the oral health of elders, as the size of this population is increasing worldwide (Jainkittivong et al., 2002). Denture stomatitis is a prevalent and longstanding problem in elders wearing removable dentures (Cunha-Cruz, 2006). Poor oral hygiene, nocturnal wear of the prosthesis, trauma, smoking, systemic conditions, allergic reactions to denture base materials and bacterial and fungal infections, particularly *Candida albicans*, have all been proposed as causal or associated factors in denture stomatitis (Budtz-Jorgensen and Bertram, 1970; Shulman et al., 2005; Zissis et al., 2006). Given that no studies showing a cause effect relationship have yet been carried out, there is presently no consensus on the etiologic factors of denture stomatitis (Barbeau et al., 2003; Emami et al., 2007).

Mechanical forces are recognized for their important role in tissue changes (Mori et al., 1997). It is believed that denture trauma, due to unstable dentures, is one of the etiological factors of denture stomatitis. Denture stomatitis is an inflammatory reaction, and the inflammatory process varies depending on the type of tissue involved, as well as the intensity and concentration of the transmitted forces. It has been demonstrated (Nakashima et al., 1994) that covering the palatal mucosa with a denture base, without mechanical pressure, reduces physiological stimulation with no histopathological changes. The histopathological changes in denture supporting tissue seem to be dependent on the strength and distribution of occlusal pressure (Mori et al., 1997). Immunohistochemical analysis of mucosal tissue involved in denture stomatitis has demonstrated a possible role of trauma in the variation of expression of the basement membrane antigens (Le Bars et al., 2001). Furthermore, it has been

shown that dentures attached to implants lead to more uniform distribution of loads to the mucosa (Preti et al., 1996). Therefore, more stable dentures, such as those with implant retention, may offer more consistent biting force vectors, thereby reducing trauma to the denture bearing mucosa.

This study is the first that aims to determine the frequency of denture stomatitis in elderly edentulous populations wearing maxillary full dentures and mandibular two-implant overdentures or conventional dentures. The frequency of denture stomatitis and the influence of classical risk factors were also investigated. Our hypothesis was that the frequency of denture stomatitis is less in elders wearing mandibular implant-retained overdentures than in those wearing conventional dentures.

MATERIALS AND METHODS

Trial Characteristics

175 edentulous participants who had previously participated in a randomized clinical trial agreed to participate in this study. The McGill University Institutional Review board approved the protocol, and informed written consent was obtained from each patient. Using a computer generated permuted block scheme, the participants were randomly assigned to receive either mandibular overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland) (IOD) or conventional dentures (CD), both opposed by new conventional maxillary dentures using a balanced occlusal scheme. Details of the randomized controlled trial have been previously described (Esfandiari et al., 2006; Perri et al., 2006). Participants who had worn their new prostheses on a regular basis in the previous twelve months were eligible for inclusion in this study. Those who had not worn their prostheses or

if the attachment system had been changed were excluded (n=2), leaving a total sample of n=173 (80 men and 93 women; mean age 72.13±4.39 years; IOD n=97 and CD n=76; Figure 1).

The outcome of this study was denture stomatitis frequency on the palatal mucosa. Based upon previous estimates of the prevalence of denture stomatitis in individuals wearing conventional dentures (approximately 40%) (Cumming et al., 1990), we calculated the necessary sample size (n=164) to detect a 20 % difference in prevalence between groups (Conventional: 40%, Implant 20%), with power of 0.80 and alpha of 0.05 (two-tailed) using Systat II and test of equality of two proportions for an unequal group size ratio of 1.28. Such a difference is clinically relevant.

Before treatment intervention, all participants were evaluated for the presence of any mucosal disease and treated, if necessary. Two independent, calibrated examiners performed oral examinations and diagnosis of denture stomatitis, according to the Newton classification (Newton, 1962): Newton Type I : localised simple inflammation usually found around the small palatal salivary glands, Newton Type II: a generalised inflammation of the denture bearing area and Newton Type III: Hyperplasic palatal surface. The diagnosis of denture stomatitis was assessed on the bearing mucosa of maxillary prostheses, because denture stomatitis is rarely seen beneath mandibular dentures (Wilson, 1998). Furthermore, since the dynamic contact of the denture teeth transmit forces to denture bearing tissues, the stability or instability of the mandibular denture can have an impact on the opposing denture bearing mucosa.

A research assistant, blind to treatment assignment, entered data into a computer database.

The association between denture stomatitis frequency with sociodemographic and classical risk factors was investigated. The demographic variables (age, sex, education), hygienic habits (nocturnal wear, denture cleaning frequency, palatal brushing, using mouth wash, denture cleanliness) and smoking habits were gathered from questionnaires and clinical exams, then categorized and summarized as dichotomous variables (Table 1). Denture cleanliness was assessed clinically according to the modified Hoad-Reddick classification (Hoad-Reddick et al., 1990): Clean (without any soft/hard debris or stain) and Dirty (with soft and hard debris or stain after washing under tap water).

To determine whether denture stability was associated with occurrence of denture stomatitis, we measured perceived denture stability, which could be a proxy measure for trauma during chewing. Satisfaction with perceived stability of the prosthesis was rated by participants using the item " How satisfied are you with the stability of your mandibular prosthesis " on 100 millimetre visual analogue scales (VAS) with anchor words of "not at all satisfied" and "completely satisfied" (Awad et al., 2003).

Mycological investigations to determine the frequency of *candida*- associated denture stomatitis were performed on a convenience sample of 48 participants. Cost issues restricted the testing of all 173 subjects. Collection of denture plaque was made by a sonication technique (Al-Fattani and Douglas, 2006; Webb et al., 2005). The recovered plaque was inoculated on Sabouraud-Dextrose 4% Agar (SD, Difco) and Trypticase Yeast Extract Agar. All cultures were incubated in a humidified incubator at 37^{o}C, 2.5 % CO_2 for 48 hours.

Candida species were identified using the germ test tube identification system induction essay, API 20 CAUX (bioMerieux) and growth on selective culture medium (CHROMagar Candida, France).

Statistical Analyses

Pearson Chi-square and Fisher's exact test (two tail) were used to compare groups for frequency of denture stomatitis, influence of risk factors on denture stomatitis and the influence of type of mandibular prosthesis on hygienic habits and cleanliness. Odds ratios and their 95% confidence intervals were calculated to determine the strength of the association between risk factors and denture stomatitis. Independent variables with results $p<0.25$ from univariate analyses were incorporated into the logistic regression analyses. Mean differences in patient satisfaction with prosthesis stability in the healthy and stomatitis groups were analyzed by an independent sample two-sided t-tests.

Pearson Chi-square and Fisher's exact test (two tailed) were used to analyse the association between frequency of denture stomatitis and dichotomized perceived stability (low satisfaction versus high satisfaction).

Differences were considered statistically significant at $P< 0.05$. All analyses were carried out using SPSS version 15 (SPSS Inc., Chicago, IL, USA).

RESULTS

The frequency of denture stomatitis was 63.6 % in the entire population. About one third of the sample had no denture stomatitis (Healthy n= 63), and the other 2/3^{rds} fell equally into Newton Type I (n=55) and Newton type II (n=51) groups. Only 4 subjects were diagnosed as Newton type III. Gender, age and level of education, as well as frequency of denture cleaning, palatal brushing, using mouth wash, maxillary denture cleanliness and smoking, were not significantly associated with denture

stomatitis (Chi-Square, Fisher's Exact Test $P > 0.05$; Table I). Inter-observer agreement on diagnosis of denture stomatitis was high (Kappa 0.87).

In a sample of 48 participants, a microbiological analysis revealed that, 22 were *Candida* yeast carriers. Three species of *Candida* were identified: *C. krusei, C. tropicalis* and *C. albicans*. No statistical difference was found between healthy subjects and those with stomatitis in *Candida* yeast carriage (P=0.60, Pearson Chi-Square).

The risk of denture stomatitis was 4.5 times greater in individuals wearing conventional dentures than in those who wore mandibular 2 implant overdentures (P<0.0001, OR=4.52 CI 2.24 to 9.14; Figure 2). There was also a significant relationship between wearing the prosthesis at night and presence of denture stomatitis (P=0.02, OR=2.70 CI 1.15 to 6.31). Elders in the implant overdenture group (VAS 81.00 ±26.5 mm) were more satisfied with the stability of their dentures than those in conventional group (VAS 71.10 ± 32.4 mm) P=0.03). There was no significant difference in frequency of denture stomatitis in participants with low perceived stability or high-perceived stability (76.7 % versus 60.8%, P=0.1).

There were no differences between the two groups in denture cleanliness (P=0.11) or frequency of denture cleaning (P=0.07).

The logistic regression model showed that only 2 independent variables, type of the prosthesis and nocturnal wear of the prosthesis, were associated with the frequency of denture stomatitis (Table 3).

DISCUSSION

We carried out this study to determine the effect of implant overdenture treatment on the occurrence of denture stomatitis in elderly edentulous individuals. We found that the type of and continuous wearing of the prosthesis predicts the presence of denture stomatitis. This supports the hypothesis that the aetiology of denture stomatitis is trauma.

Denture stomatitis is the most important outcome variable in clinical measurement of oral health in complete denture wearers (Frenkel et al., 2001), and the literature contains an impressive amount of information on the cause and treatments (Budtz-Jorgensen et al., 2000; Cross et al., 2004; Dorko et al., 2001; Golecka et al., 2006). However, a cause –effect relationship has never been shown, as most of the previous studies are observational. Many previous studies have shown a high prevalence of denture stomatitis among complete denture wearers (Barbeau et al., 2003; Budtz-Jlrgensen et al., 1996), findings that are supported in this study. Also in agreement with our previous studies (Barbeau et al., 2003; Emami et al., 2007), we found no significant relationship between denture stomatitis and classical risk factors such as sex, age, hygienic habits, denture cleanliness and presence of *Candida sp.* Our finding that continuous and nocturnal wear of prostheses increases the frequency of denture stomatitis is also consistent with the literature (Wilson, 1998). This finding is generally explained by the fact that nocturnal wear of the prosthesis can reduce the protective effect of saliva, cleaning action of the tongue and good oxygenation of the mucosa which are the key factors in the resistance of mucosal tissue to mechanical and microbiological aggression (Emami et al., 2007; Shulman et al., 2005).

The impact of mandibular implant overdentures on the frequency of denture stomatits supports the concept that denture stomatitis may be more strongly related to denture trauma than to other risk factors, such as microbiological factors. It has been shown that the extent of inflammation determines the presence of yeast infections (Barbeau et al., 2003). Therefore, inflammation could be a precursor to bacterial and fungal colonization. Previous studies were unable to detect a relationship between the isolation of yeast and the clinical appearance of denture-bearing mucosa (Wright et al., 1985). Furthermore, many investigations have demonstrated that inflammatory changes in the mucosal tissue were not produced when the palatal mucosa was covered with a denture that had no masticatory contact (Hara et al., 1996; Mori et al., 1997).

It has been suggested that incorrect vertical dimension of occlusion is a contributing factor in the occurrence of denture stomatitis (Budtz-Jorgensen and Bertram, 1970; Nyquist, 1952; Zissis et al., 2006). Since the accuracy of the vertical dimension of the participants was confirmed during follow up prosthodontic examination, we hypothesize that vertical dimension is not itself a causative factor. However, its deficiency could lead to uneven distribution of loads and traumatogenic contacts.

The results of this research suggest that continuous traumatogenic occlusal contact could increase the frequency of denture stomatitis. Our explanation of these results would be that an inflammatory reaction is the result of denture trauma. Consequently, inflammation due to trauma may create an environment favourable to microorganisms found in denture stomatitis.

The technique of combining the different types of Newton classification together in one group has been used previously in several studies on this topic (Barbeau et al., 2003; Emami et al., 2007; Shulman et al., 2005; Zissis et al., 2006). The grouping

technique does not appear to invalidate study results. In this study, there were more cases of denture stomatitis in the conventional denture group than in the implant overdenture group, for each individual Newton type."

Our finding concerning the association between denture stomatitis and perceived stability of the prosthesis shows that the proxy measure, measuring patient satisfaction with the stability of the prosthesis, is not sufficiently sensitive to measure the amount of stability required to reduce trauma during chewing.

Although all of the participants were given the same clinical instructions on methods of cleaning their dentures and their mouths, those who received the implant overdentures appeared to have a tendency to pay more attention to their oral hygiene. This information should be considered by oral health planners as an important response to new technology in elderly oral health promotion.

Further experimental studies are needed to gauge the generalizability of these findings and the potential sources of bias caused by cross-sectional analysis. It should also be noted that this population consists only of elders. Thus, the results may not be extrapolated to other age groups.

In summary, this study suggests that, in edentulous elders, better maxillary oral mucosal health may result when mandibular dentures are supported by a minimum of two implants. Implant overdentures could be effective in controlling denture stomatitis by preventing trauma to oral mucosa.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the generous contribution of Dr Kimoto, Jean-François Ross, Stephanie Wollin and Nicolas Drolet to this study. This research was funded by a CIHR Industry Grant with Straumann Canada Limited. Dr Emami is supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research.

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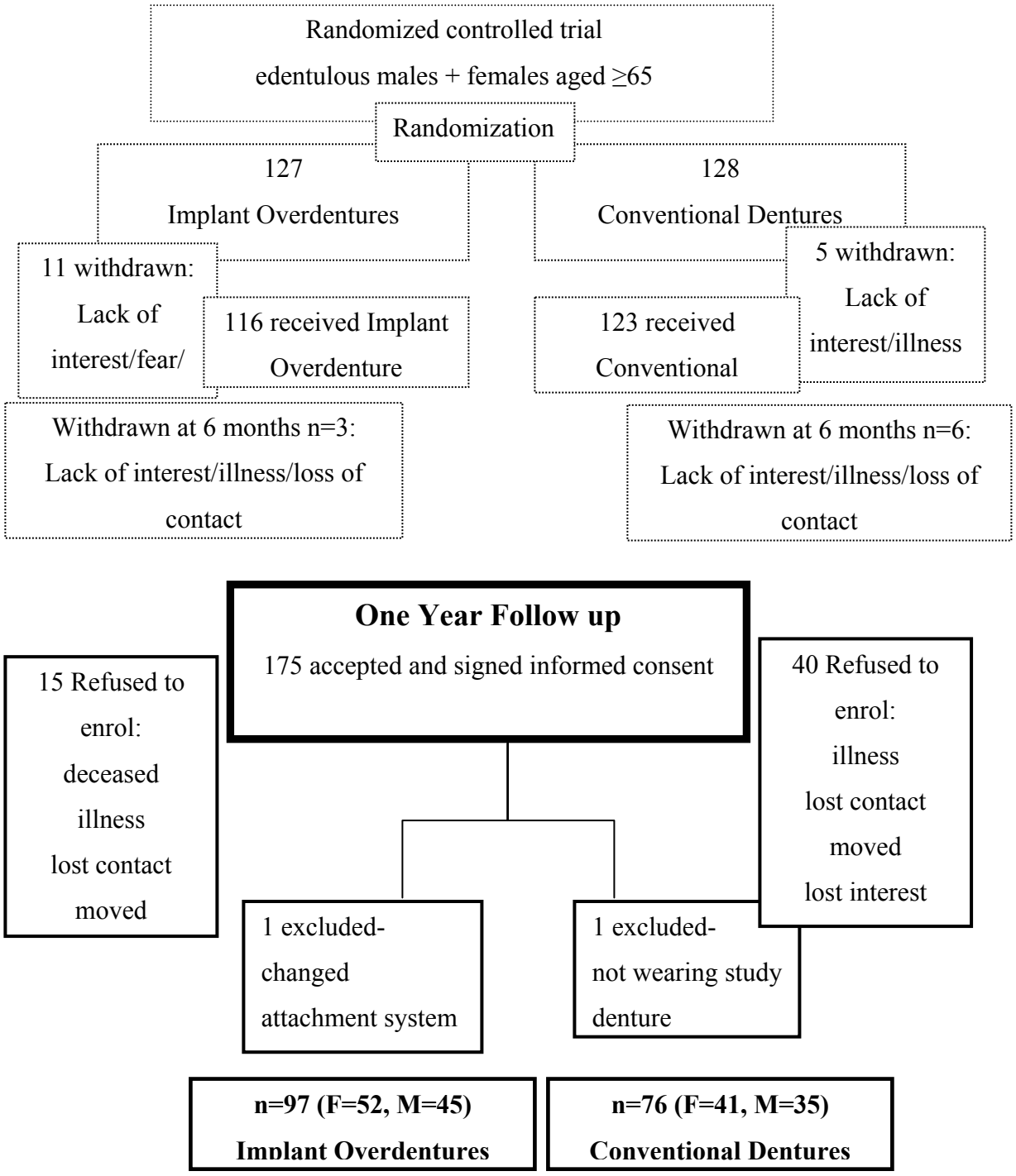

Figure 1. Study flow chart

Table 1: Risk factors associated with denture stomatitis

Explanatory variables	Healthy (% n=63)	Denture stomatitis (% n=110)
Sexe: female**	49.2	56.4
Age: more than 70**	58.7	58.2
Education: high school or less**	57.1	64.5
Nocturnal wear of prosthesis*: Yes	12.7	28.2
Denture cleaning: Less than 2 times/day**	23.8	23.6
Palatal brushing: No**	60.3	68.2
Using mouth wash: No**	49.2	56.4
Denture cleanliness: Dirty**	23.8	22.7
Smoking**	6.3	9.1
Type of Prosthesis: maxillary and mandibular conventional complete denture*	22.2	56.4
Perceived stability*: Low (less than 50 VAS)**	11.1	20.9
Presence of Candida (n=48)**	41.7 n=10	50.0 n=12

* *P* values < 0.05 (Chi-Square tests)

** *P* values > 0.25 (Chi-Square tests)

*** *P* values=0.10 (Chi-Square tests)

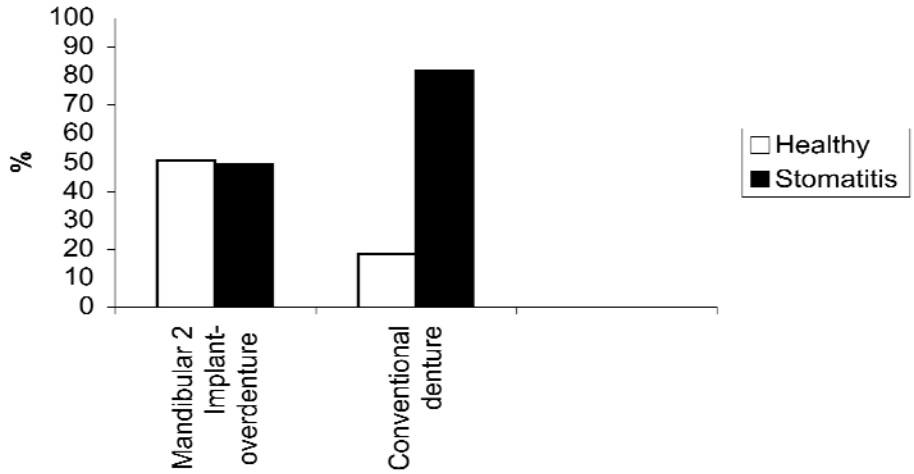

Figure 2: The impact of the type of mandibular prosthesis on the prevalence of palatal denture stomatitis

$P < 0.0001$ (Fisher's exact test)

Table 2: Unajusted and adjusted risk factors for elderlies to have denture stomatitis

Variable	*Category*	*OR (crude) (95% CI)*	*AOR ** (95% CI)*	*P value*
Type of prosthesis	Implant overdenture Conventional	1† 4.52 [a] (2.24, 9.14)	4.54 (2.20, 9.40)	<0.0001
Nocturnal wear of the maxillary prosthesis	No Yes	1† 2.70 [b] (1.15, 6.31)	3.03 (1.24, 7.40)	0.015
Perceived stability	High Low	1† 2.11[c] (0.90, 5,30)	1.60 (0.60, 4,21)	0.35

Odds ratio adjusted for the variables included in the table

† reference category

a *P* value <0.0001 Chi-Square tests

b *P* value = 0.01 Chi-Square tests

c *P* value = 0.10 Chi-Square tests

3.5 MANUSCRIPT # 5

Does sense of coherence influence the outcome of implant therapy?

Preliminary report was presented at American Association for Dental Research 37th (AADR) General Session & Exhibition

In preparation

Does sense of coherence influence the outcome of implant therapy?

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Key Words: Oral health related quality of life, sense of coherence, clinical trial, conventional dentures, mandibular implant overdentures

Abstract

The way that individuals view their lives, their comprehensibility and their ability to manage and cope with life stressors or, in other words, their sense of coherence (SOC) may influence their quality of life. Thus, SOC may be associated with the impact of prosthetic treatment on quality of life.

Objectives: 1. To investigate the association between SOC and oral health related quality of life (OHRQoL) in edentulous elders. 2. To determine factors that predict the outcome of implant therapy in an elderly edentulous population.

Methods: Data were collected and analysed cross-sectionally at a one-year follow-up from 173 edentulous elders (mean age 72.1±4.4) who had randomly received mandibular implant overdentures or conventional dentures, both opposed by new conventional maxillary dentures. The outcome variable, oral health related quality of life, was measured with the Oral Health Impact Profile (OHIP-20). Independent variables included SOC and prosthesis type, as well as socio-demographic variables. SOC was evaluated using the 13-item, Likert scale, short version of The Orientation to Life questionnaire with two anchoring responses, “never or very often”. Bivariate analyses were used to measure the association between OHRQoL and SOC. Regression models were applied to measure the extent to which the explanatory variables predict OHRQoL.

Results: No significant correlation between SOC and OHRQoL was detected

(*r*=-0.1; P=0.09). Type of treatment and gender predict oral health quality of life in this sample population, regardless of sense of coherence.

Conclusion: The results of this study suggest that, in edentulous elders, sense of coherence may not have a significant impact on OHRQoL or be a valid predictor of treatment effect.

Introduction

According to Antonovsky's salutogenic theory (1, 2), individuals with a strong sense of coherence (SOC) consider life stressors to be minimal and cope well with them, resulting in perception of better health related quality of life. Antonovsky defines SOC as follows:

"A global orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence that (i) the stimuli from one's internal and external environments in the course of living are structured, predictable, and explicable; (ii) the resources are available to one to meet the demands posed by these stimuli; and (iii) these demands are challenges, worthy of investment and engagement."

Recently, this salutogenic approach has been used as an explanatory variable to understand factors that influence oral health in different populations (3-5). The findings of some studies with adolescent dentate participants suggest that SOC may be associated with better oral health behaviours (3). Other investigations have demonstrated that sense of coherence has modifying effects on oral health related quality of life (OHRQoL). Dentate adults with a strong SOC reported better oral health quality of life than those with a weak SOC (4, 5). SOC was also found to be associated with all of the subscales of the Oral Health Impact Profile (OHIP), most strongly in the psychological discomfort, psychological disability and handicap subscales (4). This means that people might respond differently to patient-based assessment measures, not only because of a treatment effect but because they have different *comprehensibility* (ability to define life events as less stressful),

manageability (ability to deal with encountered stressors) and *meaningfulness* (the motivation to cope) (1, 2).

There is some evidence that mandibular implant overdentures improve oral health-related quality of life (6-8). However, according to the salutogenic theory, the impact of treatment might be dependent on an individual's sense of coherence. Several studies have shown that psychological factors and personality traits play an important role in the success of prosthetic treatment, especially for edentulous individuals (9, 10). Furthermore, SOC has been shown to be correlated with health behaviours in chronic general health condition (11, 12). No study has yet been carried out in which health behaviours associated with chronic oral health conditions such as edentulism are assessed using the salutogenic model. Therefore, this study aimed to assess the relationship between sense of coherence and rating of oral health quality of life in an elderly edentulous population wearing mandibular two-implant overdentures and conventional dentures. The secondary objective was to determine factors that predict the outcome of prosthetic therapy in an elderly edentulous population.

It was hypothesized that SOC correlates with oral health related quality of life and that edentulous elders with a strong SOC rate the outcome of their treatment better, regardless of type of prosthesis.

Material and Methods

The data from this study were obtained from 173 male and female edentulous elders (aged ≥65 years, mean age 72.1±4.4) who participated in a randomized clinical trial in which the impact of mandibular two-implant overdentures on nutritional status

was assessed. By using a computer generated permuted block scheme, the patients randomly received either mandibular conventional dentures or overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland) both opposed by new conventional maxillary dentures.

The McGill University Institutional Review Board approved the protocol of this study, and informed written consent was obtained from each patient prior to his/her enrolment. Information on this randomized controlled trial has been previously described (13, 14). At a one year follow up visit, participants underwent a series of assessments, including oral health related quality of life and sense of coherence. This manuscript presents the results of the one-year cross-sectional analysis of oral health-related quality of life and SOC. Based on previous findings, a total number of 86 participants is needed to achieve a power of 80% with a type I error of 0.05, for a treatment difference of 20 on the OHIP scale (7). Thus, this study was sufficiently powered to assess ratings of OHIP according to treatment received.

The 20-item Oral Health Impact Profile (OHIP-20) (6) was used to assess oral health quality of life. This 20-item questionnaire measures self-reported impairment in edentulous populations, and it includes 7 domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The items were rated on six point likert type scales (never, rarely, occasionally, often, very often or all of the time). The total range of the scale is 20-120 points, lower scores indicating better oral health-related quality of life.

Sense of coherence was measured using the short version of The Orientation to Life questionnaire (SOC-13). The feasibility, validity and reliability of this scale have been previously shown (15, 16,17). This questionnaire consists of 13 items rated on a 7-point likert scale, with two anchoring responses ‘never or very seldom’ and ‘always

or very often'. The total range of the scale is 13-91 points. A sum score of the scale was calculated by adding up the raw scores (4). Higher scores indicate a stronger SOC.

Data on gender, age, education, and economic and marital status were all obtained from a standard socio-economic questionnaire

Statistical analysis

Data analysis was carried out using SPSS software version 16.0 (SPSS Inc., Chicago, IL, USA).

The data were first subjected to descriptive statistics tests (Table 1). SOC and OHIP-20 scores were analyzed in both continuous and categorical format. Total OHIP-20 scores and total SOC scores were calculated by adding up the scores of all of the items. Using a previously described method (4) (7), individual items and sum of the items of the OHIP were dichotomized for analysis to " low negative impacts " if the impact occurred "rarely, never, occasionally" versus "high negative impacts" if the impact occurred "often, very often or all of the time".

The sample was divided into weak and strong SOC around the median SOC scores of 71. Thus, <71 was considered to be weak and 71≥ was considered to be strong. The other explanatory variables were also dichotomized (Table 2). Correlations between OHIP and SOC scores were calculated using Pearson correlation analyses. Independent-samples t-tests were used to compare the means from the total OHIP scale and each of its 7 subscales with sense of coherence scores. Independent samples t-tests were also used to compare the mean of SOC scores according to socio-demographic variables.

Chi-square analyses were applied to explore the association between OHIP impacts (low versus high) and the explanatory variables. In order to measure the strength of the association, odds ratios and their 95% confidence intervals were calculated. Those independent variables that were significantly associated with a dependent variable at the level of $P<0.25$ were included in the logistic regression analyses. Statistical significance was set at $P< 0.05$.

Results

The sample was composed of 46.2% (80) men and 53.8% (93) women. The mean age of the sample population was 72.1±4.4 years with a range of 66-88 years. The characteristics of the study participants according to treatment assignment are shown in Table 1. No differences in socio-demographic variables between the two groups were found.

The mean of total OHIP scores were 34.8±16.8. The mean of total SOC scores of the sample was 70.3±9.6. No correlation was found between total OHIP and SOC scores (r=-0.1; P=0.09).

The distribution of participants into the 2 OHIP categories by gender, age, marital status, socio-economic variables, type of the prosthesis and the dichotomized SOC is presented in Table 2. Women had almost 2 times more negative impacts than the men (OR=1.9, 95% CI 1.05 to 3.56, P<0.05) (Table 2, 4). Similarly, individuals wearing conventional dentures had significantly more risk of negative impacts than those wearing mandibular implant overdentures (OR =2.3, 95% CI 1.26 to 4.30, P<0.05) (Table 2, 4). There were no statistical differences between participants having lower OHIP negative impact and higher OHIP negative impact according to age, marital

status and the socio-economic variables. No difference was found in the frequency of oral health related negative impacts between individuals with weak or strong SOC (Table 2). The mean SOC scores for men and women were similar (71.2±9.5 versus 69.5±9.6, P=0.2). There was no association between SOC and the socio-demographic variables.

There were no differences in the OHIP total and subscale scores of individuals with weak or strong SOC, except for functional limitation (P=0.03). Elders with high SOC had assigned lower scores to this domain (Table 3). Logistic regression analysis demonstrated that only gender and type of prosthesis significantly predict oral health related quality of life ($P \leq 0.05$; Table 4).

Discussion

Oral health related quality of life is an important dimension of health among edentulous elders. We have carried out a study to test the hypotheses that oral health related quality of life is correlated with sense of coherence in edentulous elders and that, in this population, those with strong SOC rate their oral health related quality of life better after receiving new prostheses, regardless of the type. The results of this study do not support these hypotheses. We found that oral health related quality of life was independent of SOC in edentulous elders.

A number of studies, in fields other than dentistry, have investigated the association between sense of coherence and perceived health, subjective well-being, and different illnesses. These studies have not provided conclusive evidence, as some found significant associations, (18-24, 28) while others did not (25-27). A recent systematic review looking at the relationship between SOC and perceived health

indicated that SOC seems to be associated with psychological dimension of perceived health rather than the physical dimension (28). In addition, some studies suggest that disease process or medical intervention may alter the sense of coherence (25, 29, 30). Few studies have attempted to evaluate the association of SOC with oral health status (dental caries, oral cleanliness, periodontal disease) (3), oral health related behaviours (pattern of dental attendance, frequency of tooth brushing) (5) and oral health related quality of life (4). Sovolainen et al. (4) carried out a cross-sectional survey in 4039 dentate adults aged 30-64 years and analysed the relationship of oral health related quality of life and SOC. Contrary to our results, they found that individuals with strong SOC had significantly fewer negative impacts than those with weak SOC. The differences could be attributed to the characteristics of the sample, simple size estimation or the size of the population and the nature of the oral health condition. In Freire et al. (3) study, adolescents' SOC was related to their caries experience in anterior teeth. However, the relationship did not remain significant after controlling for adjusting factors .

To our knowledge, our study is the only study to have incorporated the sense of coherence variable in the analysis of treatment outcome in a sample of edentulous elders. This study adds to previous findings (6, 8, 31), indicating that the type of prosthesis has an important impact on the outcome of treatment for edentulism in elders. SOC is an individual-based coping characteristic and, as ageing implies changes in oral status such as edentulism, adaptation with these changes may be related to sense of coherence. Lack of association between oral health related quality of life and SOC after prosthetic treatment and the findings that individuals wearing mandibular implant overdenture had better OHIP scores, suggest that the type of

treatment may play a more significant role than coping characteristics in prosthetic treatment. Our finding that individuals with stronger SOC had better OHIP scores for functional limitations could mean that people with better adaptive coping mechanisms may be able to better tolerate their poorly fitting dentures. However, since the overall OHIP scores did not distinguish between people with high and low SOC, this finding should not be over emphasized. In a cross-sectional study, Heydecke et al. (32) measured various styles of coping (COPE) in an edentulous population wearing conventional dentures. Their results also indicated that problem-focused coping strategies did not have an impact on oral health related quality of life.

Our findings support the results of previous studies demonstrating sex differences in reported general health problems (33, 34) with men reporting significantly less problems than women. Furthermore, in agreement with previous studies (35), we also found no differences between the SOC scores of men and women. Therefore, coping mechanisms may not be the cause of difference in outcomes between the sexes. Observed differences could be more related to physiology or other psychological parameters rather than coping mechanism (36, 37).

A number of sources of bias could influence these results. The sample was self-selected (participants in an RCT). Therefore, these results should be interpreted with caution. Furthermore, the cross-sectional analysis of the data did not allow for the assessment of change in SOC due to a new treatment although, to date, evidence indicates that SOC is stable in the elderly population (38).

Conclusions

The results of this study suggest that, in edentulous elders, there may be no association between sense of coherence and oral health related quality of life. It seems that sense of coherence is not a prerequisite for successful management of edentulism. Type of treatment and gender predict oral health quality of life, regardless of sense of coherence.

Acknowledgments

This study was funded by CIHR Industry Grant # UCR-36052 with Straumann Canada Limited and by the ITI foundation. Dr Emami is supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research.

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Table 1. Descriptive Statistics at one year-follow-up according to treatment allocation

Variable	CD* n (%) 76 (43.9)	IOD** n (%) 97 (56.1)	Total n (%) 173 (100)
Gender			
Males	35 (46.2)	45 (46.4)	80 (46.2)
Females	41(53.8)	52 (53.6)	93 (53.8)
Age group			
66-69	25 (32.9)	27(27.8)	52 (30.1)
70-79	46 (60.5)	61 (62.9)	107 (61.8)
80-89	5 (6.6)	9 (9.3)	14 (8.1)
Marital status			
Single	4 (5.3)	4 (4.1)	8 (4.6)
Married	45 (59.2)	45 (46.4)	90 (52.0)
Separated/divorced/Widow	27 (35.6)	46 (47.4)	73 (42.2)
No answer	0 (0.0)	2 (2.1)	2 (1.2)
Education			
Elementary/ High school	46 (60.5)	59 (60.8)	105 (60.7)
College/ University	29 (38.2)	37 (38.1)	66 (38.2)
No answer	1 (1.3)	1 (1.0)	2 (1.2)
Income			
< 40000	44 (57.9)	67 (69.1)	111 (64.2)
≥ 40000	21 (27.6)	22 (22.7)	43 (24.9)
No answer	11 (14.5)	8 (8.2)	19 (11.0)

*CD Conventional denture **IOD Implant overdenture

Table 2. Bivariate analyses at one year-follow-up evaluating the association between oral health related quality of life and various variables

Explanatory variables	Low negative impacts %	High negative impacts %	P values
Gender:			
female	46.2	62.5	0.02
male	53.8	37.5	
Age:			
≤70	39.8	43.8	> 0.25
>70	60.2	56.2	
Education:			
High school or less	62.4	61.2	> 0.25
College or more	37.6	38.8	
Marital status:			
Single/divorced/widow	44.1	52.5	> 0.25
Couple/married	55.9	47.5	
Living status:			
Alone	36.6	43.8	> 0.25
Not alone	63.4	56.2	
Income:			
< 40000	64.5	63.8	0.23
≥ 40000	35.5	36.2	
Employment status:			
Retired/Unemployed	89.2	82.5	0.20
Employed	10.8	17.5	
Type of prosthesis:			
Conventional	34.4	55.0	0.005
Mandibular implant overdenture	65.6	45.0	
Sense of coherence:			
Weak	44.1	48.8	> 0.25
Strong	55.9	51.2	

Table 3. Comparison of OHIP scores according to the sense of coherence

Parameter	Low SOC n=83	High SOC n=90	P value
OHIP Subscale	**Mean**	**Mean**	
Functional limitation	7.9±3.6	6.8 ±3.3	0.03*
Physical pain	8.6 ±4.6	7.5 ±4.1	0.09
Psychological discomfort	3.7 ±2.5	3.3 ±2.1	0.34
Physical disability	6.8 ±3.9	5.8 ±2.9	0.07
Psychological disability	3.8 ±2.2	3.4 ±2.0	0.26
Social disability	3.7 ±2.2	3.4 ±2.1	0.43
Handicap	2.7 ±1.7	2.5 ±1.6	0.30
Total OHIP scores	37.2 ±18.2	32.7 ±15.3	0.08

*Independent samples t test

Table 4: Logistic regression analysis showing unadjusted and adjusted odds ratios and 95% confidence intervals for variable related to oral health related quality of life

Variable	Category	OR (95% CI)	AOR* (95% CI)	P value
Type of prosthesis	Implant overdenture Conventional	† 2.33 (1.26, 4.30)	† 2.38 (1.27, 4.47)	0.007
Gender	Male Female	† 1.93 (1.054, 3.56)	† 1.89 (1.00, 3.58)	0.050
Employment status	Unemployed Employed	† 1.76 (0.73, 4.21)	† 1.48 (0.59, 3.68)	0.40
Income	≤40000 >40000	† 1.03 (0.55,1.92)	† 1.00 (0.52,1.94)	0.99

*Odds ratio adjusted for the variables included in the table

† Reference category

3.6 MANUSCRIPT # 6

Perceived sleep quality among edentulous elders

Preliminary report was presented at International Association for Dental Research (IADR) 87th General Session & Exhibition

In preparation

Perceived sleep quality among edentulous elders

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Key Words: Randomized prospective study, Edentulism, Sleep, Oral health related quality of life, Elders

Abstract

Poor sleep quality is common among elders. Anatomical changes associated with edentulism or sleeping without dentures are thought to negatively influence and disturb sleep.

Objectives: 1. To determine the self-reported sleep quality and sleepiness in edentulous elders, independent of nocturnal denture wearing. 2. To examine if perceived sleep quality is associated with oral health related quality of life.

Methods: Data were collected at a one-year follow-up from 173 healthy edentulous elders (mean age 72.1±4.4) who had participated in a prospective randomized controlled trial and randomly received new mandibular conventional dentures or implant retained overdentures. Subjective sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI). The global PSQI score ranges from 0 to 21, with higher scores indicating poorer sleep quality. The Epworth Sleepiness Scale (ESS) was used to measure the level of perceived daytime sleepiness, and scores ≥10 (range 0-24) indicated sleepiness. Karolinska Sleepiness Scale measured the participant's sleepiness at a given moment in time. Greater scores indicated subjective sleepiness. Oral health related quality of life was measured with the Oral Health Impact Profile (OHIP). Explanatory variables for sleep quality included perceived general health, perceived oral health, socio-demographic variables, type of prosthesis and nocturnal wearing of dentures. Perceived general health was evaluated through the SF-36 questionnaire. Results were analysed using bivariate and multivariate statistical analyses.

Results: The average global sleep quality Pittsburg index was 4.8 ± 3.5, and 55.3% of the participants scored in the good sleepers range (Global sleep-quality index < 5). Elders with low perceived health and women had significant poorer sleep than those with high perceived health and men. There were no differences in sleep quality or perceived sleepiness of edentulous elders according to their socio-economic characteristics or type of prosthesis.

There was no difference in sleep quality or daytime sleepiness between those who wore their dentures at night and those who didn't ($p>0.05$). Participants with low related oral health quality of life were almost 4 times sleepier during the day than those with high related oral health quality of life ($p=0.0034$, χ^2; OR =3.8 CI 1.5 to 9.8). The two predictors of sleep quality were perceived health and oral health related quality of life (Linear regression, $p=0.02$ and $p= 0.001$ respectively).

Conclusion: These results suggest that healthy edentulous elders, independent of nocturnal wearing of their dentures, are quite good sleepers. However, they may sleep better if they perceive fewer problems with their dentures. Further investigation is needed to explore these findings.

Introduction

Sleep complaints are common in elders (1, 2). It is reported that sleep disturbances affect more than 50% of individuals aged 65 years or older (2-5). The duration, the quality and the efficiency of sleep decrease as we get older (6, 7). Poor sleep quality results in excessive daytime sleepiness, impaired health status, depressive symptoms and lowered quality of life, as well as decreased satisfaction with life, mood and work performance (8-12). Alternatively, poor health, low quality of life and low life satisfaction may influence sleep pattern (4, 13).

Aging itself is not a cause of sleep complaints (4, 5, 14, 15). Several factors associated with aging contribute to or cause sleep disturbances in elderly populations. These factors include: medical and psychiatric diseases, medication, circadian rhythm disturbances, changes in lifestyle, such as daytime inactivity, and age-related anatomical modifications (4, 13, 16-19).

Recent findings suggest that complete edentulism and sleeping without dentures favor disturbed sleep and sleep disordered breathing (20-23). Several factors favour upper airway obstruction during sleep and increase the risk of apnea, hypopnea and sleep-disorderd breathing (24, 25). These include: a reduction in the retropharyngeal space associated with impaired function of the genioglossus and other upper airway dilatation muscles, pharyngeal inflammation due to dentures wearing, as well as loss of vertical dimension of occlusion. However, studies investigating the sleep quality of edentulous elders are scarce. Therefore, the present study sets out to obtain baseline information on the sleep quality of a population of edentulous elders and to

investigate differences in the sleep characteristics of this population in relation to socio-demographic status, perceived general health, type of dental prosthesis, nocturnal wearing of dentures and oral health related quality of life.

The second objective was to test the hypothesis that there is an association between the sleep quality and the oral health related quality of life.

Materials and Methods

The study involved 173 ambulatory, healthy male and female edentulous elders (aged ≥65 years) who had previously participated in a randomized clinical trial in which the impact of mandibular two-implant overdentures on nutritional status was assessed. By using a computer generated permuted block scheme, the patients randomly received either mandibular conventional dentures or overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland) and new conventional maxillary dentures.

Ethical approval was obtained from the McGill University Institutional Review Board and informed written consent was obtained from each participants prior to his/her enrollment in the study. Eligibility criteria flow chart of the study and other information on this randomized controlled trial has been previously described (26-29). At a one-year follow up visit, participants underwent a series of assessments including sleep quality and oral health related quality of life. This manuscript presents the results of the one-year cross-sectional analysis of oral health-related quality of life and sleep quality. Based on previous findings, 86 participants are needed to achieve a power of 80% with a type I error of 0.05, for a treatment difference of 20 on the oral

health related quality of life scale (30). Thus, this study was sufficiently powered to assess ratings of the oral health related quality of life according to treatment received.

Several instruments have been used to assess sleepiness and sleep quality including: the Pittsburg Sleep Quality (PSQI), the Epworth Sleepiness Scale (ESS) and the Karolinska Sleepiness Scale (KSS). The validity and reliability of these instruments have been reported (31-34).

The PSQI was administered to assess sleep quality and disturbances over a one-month interval. This self-administrated questionnaire consists of 19 items which generate seven component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications and daytime dysfunction. Each of the items is weighted equally on a scale of 0 to 3. Increasing scores indicate greater sleep difficulty. The seven component scores are then summed to obtain a global PSQI score, with a range of 0-21; higher scores indicate worse sleep quality, and a global PSQI score ≥5 signifies poor sleep quality.

The ESS was used to measure the level of perceived daytime sleepiness, and scores ≥10 (range 0-24) indicate sleepiness.

Sleepiness was also measured using the KSS. This scale measures the participant's state of sleepiness at a given moment in time and contains 9 points with end-points "extremely alert and very sleepy effort to stay awake, fighting sleep". Higher scores indicate greater sleepiness.

Oral health quality of life was measured with the 20-item Oral Health Impact Profile (OHIP-20) (35) which includes 20 questions regarding denture problems falling into 7 domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Responses were

provided on six-point Likert scale, with the following anchors “never” and “all of the time”. The total range of the scale is 20-120 points, with lower scores indicating better oral health-related quality of life. Good reliability and validity has been shown for this instrument (30, 36, 37).

Perceived general health was measured with the Physical Component Summary (PCS) measure of the SF-36 questionnaire (38).

Socio-demographics, parasomniac symptoms (snoring, interrupted breathing during sleep) and nocturnal denture wearing habits were all obtained through questionnaires.

Data analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 15.0 (SPSS Inc., Chicago, IL, USA).

Descriptive statistics were produced to characterize the sleep status of the study population (Table 1,2).

The Physical Component Summary (PCS) scores of the SF-36 questionnaire were dichotomized into low perceived general health (≤50) and high perceived general health (>50) according to the Canadian Normative Data for the SF 36 (39, 40) (Table 3).

The total OHIP-20 and each of the domain scores were calculated by adding up the scores of all of the items for each participant. OHIP data were analyzed in both continuous and categorical formats. For the categorical analyses, the items were dichotomized into “low negative impact” and “high negative impact”, according to whether the problem occurred “rarely, never, occasionally” versus “often, very often or all of the time” (Table 3).

Intergroup comparisons of sleep parameters were made using two-tailed independent *t* tests and one-way analyses of variance (ANOVA) (Table 3). Those independent variables with results of $p<0.25$ from the bivariate analyses were incorporated into the linear regression analyses (Table 4).

The level of daytime sleepiness measured by the ESS were dichotomized according to an ESS score more than two standard deviations (SD) from the mean reported in a normal population (41). Chi-square tests were applied to explore the association between oral health related quality of life and the daytime sleepiness. Odds ratios were used to measure the strength of the associations. Two-independent samples tests were used to evaluate the association between OHIP scores (total and subscale domains) and ESS scores (Table 5).

A two-tailed value of $p\leq0.05$ was chosen to indicate statistical significance.

Results

Ninety-three women and 80 men, with a mean age of 72.1 (± 4.4) participated in this study.

Self-reported sleep characteristics of participants are presented in Table 1 and 2.

The average global Pittsburg Sleep Quality Index was 4.7 ± 3.5, and 55.3 % of the participants scored in the good sleepers range (Global PSQI < 5). Only 6.4% of the participants presented a global PSQI score≥10 (indicator of mean score of individuals with insomnia). Fourteen percent of participants had EES score≥10 indicating daytime sleepiness. Only 1.4 % of participants had an ESS score≥ 16 indicating excessive daytime sleepiness and potential risk of obstructive sleep apnea. Forty-three percent of participants reported that they snored during sleep and 8.2 % of them stopped breathing while asleep.

The associations between perceived sleep quality, sleepiness and population characteristics are presented in Table 3. Women had significantly poorer sleep than men (Global PSQI mean 5.3±3.9 versus 4.0±2.8; p=0.02). There were no differences in sleep quality or perceived sleepiness of edentulous elders according to their socio-economic characteristics and type of prosthesis. Sixteen percent of the participants wore dentures at night. There was no difference in sleep quality or daytime sleepiness between those who wore their dentures at night and those who didn't ($p>0.05$). Elders with low perceived general health had poorer sleep than those with high perceived general health ($p<0.05$). There were significant differences in EES and KSS mean scores (Independent sample t-test, p=0.003 and p=0.02 respectively) in those

participants for whom wearing dentures had a negative impact on their quality of life and for whom didn't have a negative impact.

Regression analyses showed that perceived general health and oral health related quality of life predict sleep quality and daytime sleepiness (Table 4).

Those with low oral health related quality of life were almost 4 times sleepier during the day than those with high oral health related quality of life ($p=0.003$, χ^2; OR =3.8 CI 1.5 to 9.8). Further analyses revealed that this difference exists for all OHIP domains, however it was only statistically significant for functional limitation OHIP domain (t-test, $p=0.01$; Table 5).

Discussion

To our knowledge, this is the first study which aims to determine the association between sleep quality and oral health related quality of life in edentulous elders.

We found that poor sleep quality was associated with low oral health quality of life in healthy elders population. In this study, we examined the sleep quality and subjective sleepiness reported by a population of edentulous elders. We found that more than half of our population of edentulous elders have good sleep quality, independent of nocturnal prosthesis wearing. The mean Epworth Sleepiness Scale scores in this population were similar to the mean scores previously reported in a normal elders population (41). Furthermore, our results are consistent with report from previous studies demonstrating a prevalence sleep problems in 10 to 50% of elders (1). The subjects enrolled in this study were generally free of underlying psychiatric illness or major medical illnesses. Moreover, more than half of them rated their general health as high. This could explain the overall good sleep characteristics of this elder

population compared to other studies with older populations. The results of our study confirm previous findings showing that sleep parameters are significantly related to health status and gender (2, 13, 42).

Although there may be a discrepancy between self reported sleep quality and laboratory sleep measurements (43, 44), we used questionnaire–based scale for measurement of sleep propensity in elders because of cost and complexity of sleep laboratory measurements. Furthermore, overall sleep quality is a principally self-evaluated concept, and cannot be totally explained by laboratory-based measurements. In addition, according to some studies self reported-measurements are significantly correlated with laboratory measurements of sleep quality (41, 43).

Despite the high prevalence of sleep disturbances in elders, few studies have assessed sleep quality in edentulous elders. Few studies showed that obstructive sleep apnea (OSA) could be seen in edentulous patients not wearing their prosthesis at night (22). In our study, ESS scores higher than 16 indicating increased risks of OSA have been found only in 3% of participants and 8.7% reported to stop breathing while sleeping. We also didn't find any difference in sleep quality or daytime sleepiness between those who wore their dentures at night and those who didn't. These findings could possibly suggest that edentulous participants in our study were not at risk for obstructive sleep apnea. As nocturnal wearing of prostheses increases the frequency of denture stomatitis, and because in this study we didn't find a tendency of sleep breathing disorders among healthy edentulous elders, we still advise to remove prostheses at night, unless individuals are at high risk for sleep-disordered breathing.

In order to have valid diagnostic of obstructive sleep apnea, we needed to record sleep and calculate Apnea Hypopnea Index (45).

It was interesting to see that this association was seen for functional limitation. Despite uncertainty about the issues of this correlation, these findings could suggest that oral health may account for some of the variability in sleep quality and daytime sleepiness. However, further studies are needed to clarify the underlying mechanism of this association.

The results of this study should be interpreted with consideration of some limitations. First, the sample was self-selected therefore the extent to which our findings can be generalized to general population is not clear and possibly result in underestimation of prevalence of sleep disturbance in our study.

Second, measures were self-reported, making the results prone to reporting or recall bias. There is also a potential overestimation of the true association between different self-reported outcomes.

Third, the analyses were cross-sectional, making inference about the direction of the relationships not possible. Furthermore, we could not compare the evolution of sleep quality regarding their dentate status. Further investigations using longitudinal designs may be useful in determining the relationship between elders sleep pattern and edentulism.

Conclusion

The results of this study suggest that healthy edentulous elders, independent of nocturnal wearing of their dentures, are quite good sleepers. However, negative impacts of wearing denture on quality of life may influence sleep quality and daytime sleepiness. Further investigation is needed to explore these findings.

Acknowledgments

This study was funded by CIHR Industry Grant # UCR-36052 with Straumann Canada Limited and by the ITI foundation. Dr Emami is supported by a stipend from the CIHR Strategic Training Program in Applied Oral Health Research.

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Table 1. Self-reported sleep characteristics in 173 edentulous elders

	Min	Max	Median	Mean	Standard deviation
Global Pittsburg Sleep Quality Index	.00	21.00	4.00	4.70	3.50
Epworth Sleepiness Scale	.00	20.00	4.00	5.33	3.90
Karolinska Sleepiness Scale	1.00	8.00	2.00	2.31	1.50

Table 2. Mean PSQI (Pittsburg Sleep Quality Index) component scores and global score in 173 edentulous elders

Parameter	Mean±SD
Sleep quality	0.83±0.8
Sleep latency	0.85±0.9
Sleep duration	0.80±0.9
Habitual sleep efficiency	0.58±0.9
Sleep disturbance	1.10±0.5
Use of sleeping medication	0.40±0.9
Daytime dysfunction	0.33±0.6
Global PSQI	4.70±3.5

Table 3. Bivaraite analyses evaluating the associations between perceived sleep quality, sleepiness and various variables

Variable	Global PSQI Mean	ESS Mean	KSS Mean
Gender			
Females (n=93)	5.3±3.9*	5.1±3.8	2.4±1.7
Males (n=80)	4.0±2.8	5.5±4.0	2.2±1.5
Age group			
66-69 (52)	4.4±2.7	5.2±3.7	2.0±1.3
70-79 (107	4.8±3.9	5.4±3.7	2.3±1.5
80-89 (14)	5.7±3.1	5.8±3.1	2.3±0.8
Marital status			
Single (n=8)	3.6±3.1	6.2±5.0	3.8±1.9
Married (n=90)	4. 3±2.8	5.2±3.3	2.0±1.2
Separated/divorced/Widow (n=75)	5.2±4.2	5.4±3.9	2.3±1.5
Education			
Elementary/ High school (n=66)	5.0±3.6	5.5±3.8	2.3±1.4
College/ University (n=105)	4.3±3.4	5.2±3.5	2.1±1.4
No answer (n=2)	3.5±4.9	3.5±2.1	1.5±0.7
Income			
< 40000 (n=111)	4.7±3.5	5.2±3.6	2.3±1.5
≥ 40000 (n=43)	4.3±2.3	5.7 ±3.8	2.3±1.4
No answer (n=19)	5.6±5.1	4.8±4.1	2.3±1.8
Type of the prosthesis			
Conventional (n=77)	5.1±3.9	5.7±4.1	2.5±1.5
Implant (n=96)	4.3±3.0	4.9±3.7	2.1±1.3
Nocturnal wearing of the prosthesis			
Yes (27)	4.4±3.1	5.2±3.5	2.4±1.3
Non (146)	4.7±3.5	5.3±4.0	2.2±1.5
Negative impact of wearing denture on quality of life			
Low (n=98)	4.4±3.0	4.6±3.4***	2.0±1.2*
High (n=75)	5.2±4.0	6.3±4.2	2.6±1.6
Perceived general health			
Low (n=89)	5.4±3.9**	6.0±4.2*	2.7±1.7****
High (n=83)	3.9±2.6	4.7±3.4	2.0±1.2

Independent t-test *P=0.02 ** P=0.01 ***P=0.003 ****P=0.001

Table 4. Predictors of sleep quality and daytime sleepiness among edentulous elders

Outcome	Variable	Coefficient	P value	95% CI for Coefficient
Sleep quality	Type of Prostheses[a]	0.40	0.494	-0.74, 1.53
	Gender[b]	0.81	0.148	-0.29, 1.92
	Perceived general health	-1.27	0.022	-2.35, -0.20
	Oral health related quality of life	0.06	0.001	0.02, 0.09
Daytime sleepiness	Type of Prostheses	0.51	0.400	-0.64, 1.67
	Gender	0.54	0.358	-1.60, 0.52
	Perceived general health	-1.39	0.017	-2.53, -0.253
	Oral health related quality of life	1.68	0.005	0.53, 2.80

[a]0=CD, 1=IOD

[b]0=Males, 1=Females

Table 5. Comparison of OHIP scores according to perceived daytime sleepiness scores (EES) in 173 edentulous elders

Parameter	EES <10	EES ≥10
OHIP Domains	Mean ± SD	Mean ± SD
Functional limitation	7.0±*3.4	9.0± 3.9
Physical pain	7.8± 4.0	9.7±5.8
Psychological discomfort	3.4± 2.1	4.2± 3.3
Physical disability	6.1± 3.0	7.3 ± 5.2
Psychological disability	3.4 ± 1.9	4.4 ± 2.4
Social disability	3.4 ± 1.6	4.7 ± 3.9
Handicap	2.4 ± 1.3	3.3 ± 2.8
Total OHIP scores	33.5 ± 14.6	42.7 ± 25.6

Independent samples t-test, P=0.01

CHAPTER 4

Discussion and directions for future research

In this research project, several questions have been raised and answered:

4.1 Does edentulism affect general health?

In order to answer this question, a literature review was conducted. According to the literature, there is a relationship between edentulism and general health [82, 83, 86, 225]. This association is bi-directional and involves many pathways. Most studies suggest that tooth loss can affect physical health mainly through the nutrition pathway [7, 68, 99, 226-229]. Edentulism may affect nutrient quality and intake in a way that may increase risk of systemic diseases [99, 230]. However, the interpretation of causality is complicated for several reasons. Most of these studies have been cross-sectional or prospective cohorts studies with relatively small sample sizes and based on short follow-up periods [39, 80, 92, 227, 231, 232]. Many of these studies have been carried out among vulnerable populations, such as hospitalized elders or those in residential homes [233]. Although many factors, such as health behaviours, geographic location and socio-economic status could confound the association between general health and edentulism, several of these studies did not adjust for those potential confounders [82, 83, 234, 235]. Furthermore, general health measurements were often not well described or standardized [236]. Feasibility, reliability and validity of the measurement instruments were not always properly

investigated. In addition, the choice of variable to include in a general health assessment was dependent on the researcher's theoretical beliefs and experiences about the issue.

Therefore, more studies with sufficient sample sizes, adequate follow up periods and the appropriate control of confounders are needed to better understand the relationship between tooth loss and general health. These studies should include a comprehensive assessment of all dimensions of health, including oral, physical and mental health. Assessment should be based on standardised and validated assessment methods. These studies will shed light on the pathophysiologic association between oral health status and systemic health outcomes.

4.2 Does type of removable prosthesis affect general health?

To address this question, we carried out a systematic review and also followed, up to one year, the perceived general health of individuals who randomly received mandibular implant overdentures or conventional dentures.

Our systematic review demonstrated that the answer to this question is hampered by a lack of randomized controlled studies. The first and the only study evaluating the impact of mandibular implant overdentures on perceived general health [212] failed to show an association between the type of prosthesis and perceived general health. In this study, as in ours, edentulous elders rated their general health at a level similar to the general Canadian population in that age group. Since Canadian normative data are not stratified by oral health status and because the rate of edentulism in Canadian elders, is 35%, the actual impact of edentulism on general health remains unclear.

Regardless, these finding confirm that the study sample is representative of the Canadian elder population [237].

The perceived general health of this population decreased over time, which may be expected as people age. However, we found that individuals wearing new conventional dentures reported significant decreases over time in their physical perceived health domains, while those with mandibular two-implant retained overdentures did not. Although several studies have concluded that the psychological and social function of implant retained prostheses are important [4], the present findings suggest that the impact of implant retained overdentures on perceived general health is more strongly related to function.

Assessment of the type and extent of an individual's disability can assist clinicians in integrating patient values into therapeutic decisions. Furthermore, effective interventions can allow individuals to reach their expectations, despite their physical disabilities. Using SF-36 as a measurement instrument permitted us to pinpoint the dimensions of health that affected elders in our study population the most. This classic instrument is widely employed in clinical trials with patient based outcomes [134, 238]. However, generic instruments require larger sample sizes than disease or site-specific instruments to reduce error and increase study power [131, 239]. Disease or site-specific instruments can reduce the size of the sample by 20-40%, as well as reducing the costs [240].

In this study, the lack of significant differences between group in SF-36 scores could be due to lack of instrument sensitivity and a too small sample. Further studies with adequate sample size and using a more sensitive instruments, may clarify whether poor general health is associated with the inadequacy of oral prosthesis to optimize nutrition, physical disability and general health of edentulous elders.

Qualitative studies should also be carried out to generate hypotheses on how edentate individuals assess the relationship between their oral health and general health.

4.3 Does type of removable prostheses affect oral health related quality of life?

In addition to mortality, morbidity, cost-effectiveness and satisfaction with care, quality of life has become a key outcome parameter to assess the beneficial effects of therapeutic modes and interventions.

Although the impact of edentulism on patients' quality of life can be minimised by helping them adapt, raising individuals' expectations of oral health is the core of health promotion and an important part of the "professional consciousness". Therefore, we should not only adopt health care strategies that improve all dimensions of well being, but also we should aim to maintain these improvements.

The design of this study permits us to quantify change in oral health related quality of life over time. Our results indicate that participants, who wore mandibular two-implant retained overdentures compared to those who wore new conventional dentures, had higher oral health related quality of life. The magnitude of change from baseline to one year was 1.7 times higher for those in the implant group that in the conventional denture group. This improvement was statistically significant and clinically meaningful. Furthermore, we demonstrated that type of prosthesis, independent of salutogenic factors such as sense of coherence (SOC), was a significant predictor of oral health quality of life. To our knowledge, our study is the only study to have incorporated the SOC variable in the analysis of treatment

outcome in a sample of edentulous elders. SOC is an individual-based coping characteristic and, as ageing implies changes in oral status, adaptation to these changes may be related to sense of coherence. Lack of association between oral health related quality of life and SOC after prosthetic treatment suggests that oral health may likely be more related to type of treatment than to coping characteristics.

These findings support the body of evidence that mandibular two-implant overdentures improve oral-health quality of life for elders. However, the results of our meta-analysis indicate that there is limited number of randomized clinical trials to demonstrate this superiority. In addition, with regard to the magnitude of effect, the results of this meta-analysis were inconclusive, mainly because of heterogeneity in the included studies. Furthermore, there are still several questions to be answered:

-Do patient ratings of oral health related quality of life change over the long term?

-Which dimensions of quality of life are reported as the worst and best over time?

-What are the care strategies for those individuals whose expectations of health care are unrealistically high or low?

These considerations point to the fact that pragmatic randomized clinical trials are needed to assure the relevance of randomized controlled study results for real-world situation. In addition, studies are needed for adequate assessment of all of the dimensions of quality of life.

4.4 Does type of removable prosthesis affect oral health?

Maintaining the health of oral tissues is a key factor for healthy functioning of the oral system. Denture stomatitis is a prevalent and unresolved mucosal problem in elders

who wear removable dentures. Although a cause–effect relationship of this persistent oral disease and oral candidosis has never been established, several elders still receive antifungal treatment without evidence that it offers a long-lasting improvement [241].

This study was the first randomized controlled trial to determine the predictors of denture stomatitis. We showed that the type of an oral prosthesis and its continuous wearing predicts the presence of denture stomatitis. The risk of denture stomatitis was 4.5 times greater in individuals wearing conventional dentures than in those who wore mandibular two- implant overdentures. The results of this study confirm previous findings regarding the lack of association between denture stomatitis and oral candidosis [153, 157]. The findings also support those from studies that demonstrated a possible role of trauma in the aetiology of denture stomatitis [242].

In order to treat denture stomatitis and resolve this clinical problem, randomized prospective cohort studies should be carried out, in which the transforming process of healthy mucosa to pathogenic mucosa can be evaluated.

4.5 How does edentulism affect sleep quality?

Since the literature has suggested that complete edentulism and sleeping without dentures favors disturbed sleep [189, 196], we aimed to clarify the role of oral health status and sleep quality in this project.

We obtained baseline information on the sleep quality of edentulous seniors and assessed differences in the sleep characteristics of this population in relation to socio-demographic status, perceived general health, type of dental prosthesis, nocturnal wearing of dentures and oral health related quality of life.

We found that more than half of this sample population had good sleep quality, independent of nocturnal prosthesis wearing. We also found significant correlations between oral health related quality of life and almost all of the measures of sleep quality. We demonstrated that poor sleep quality was associated with low oral health quality of life.

These findings suggest that oral health may account for some of the variability in sleep quality. This may form the basis of a qualitative study, in which we could learn more about underlying mechanisms. If sleep improvement could be achieved by better oral health status and oral health related quality of life, without the need for supplementary medications, this could have a major impact on the daily lives of edentulous elders.

Further investigations using longitudinal designs will help to determine the relationship between sleep pattern and edentulism in elders.

4.6 Study power

In this PhD project, we carried out a meta-analysis, which is a rigorous analysis of the highest quality therapeutic studies on the topic. According to the results of our meta–analysis, this study is the first randomized trial comparing oral health related quality of life and perceived general health of individuals who wear conventional dentures or implant overdentures up to one year follow-up. Follow-up randomized studies have the ability to: firstly, establish a temporal sequence of events between potential causative variables and treatment effects; secondly, randomisation reduces the influence of confounding factors. With a sufficient number of participants to permit

between group comparisons, it becomes possible to attribute a cause–effect relationship between type of treatment and study outcomes.

4.7 Study Limitations

External validity

"*Between measurements based on RCTs and benefit ... in the community, there is a gulf which has been much under-estimated."*

A.L. Cochrane 1971

Although randomized controlled trials are the most reliable designs for determining treatment effects, their external validity is inevitably less than desired. Therefore, the generalisation of these study results to general populations must be interpreted with some caution, as this sample was self-selected. Differences in age, race, ethnicity, culture, geographic region and access to health care services, as well as macro-level variables, could influence the perception of individuals in defining their value and expectation of health and quality of life. Clearly, a more complete understanding of the influence of these factors will require well designed prospective studies that consider a full spectrum of socio-cultural variation in testing the effectiveness of therapeutic interventions.

Internal validity

In this trial, blinding of care providers or participants to type of treatment and outcome was not possible because of the nature of implant therapy and use of patient-

based outcomes. However, those who entered and analyzed the data were blind to treatment allocation.

The measures were self-reported, making the results prone to reporting or recall bias. Thus, the size of the effect could be overestimated since it could depend on factors such as the setting of the intervention, patient preference and placebo effects.

Attrition and dropouts in long term threaten the continuity of this study, and we need to refine our strategies to retain all surviving participants on the long term.

In this project variables relating to sleep, denture stomatitis and sense of coherence were gathered from those who accepted and signed an informed consort for the follow-up study. Therefore, at one-year, data were analysed cross-sectionally. Thus, they cannot address potential causal linkages or be used to draw inference about the direction of the relationships. However, since the study design is longitudinal, the one-year data will serve as baseline for the future.

Clinical relevance

Comprehensive economic assessments of health care interventions are important elements for clinical decision–making. In this study, economic analyses were not included.

We also need additional pragmatic studies on this topic, to assure that results of RCTs are generalizable for routine practice.

4.8 Implications of these results for health care policy

Although the relationship between edentulism and general health remains unknown, the public health implications of edentulism should be recognized, given the global prevalence of edentulism.

Several strategies [243], as well as the five principles of the Ottawa Charter [244], should be applied to improve the overall well-being and quality of life of edentate elders. These principles include building relevant health public policies, strengthening community action programs, developing personal skills and re-orienting health services for maximum effectiveness.

In brief, policy makers' perceptions about oral health and its impact on health promotion should be increased to ensure the inclusion of oral care delivery systems and expansion of dental insurance coverage in health promotion programs. Furthermore, public health services should capitalize on appropriate and efficient social, educational and health care programs to prevent or delay edentulism and to improve individuals' attitudes toward dental care.

Clinicians should be encouraged to promote safe and effective treatments for edentulous elders. Health care professionals should reinforce critical health messages to their patients to promote a healthy life style that includes a healthful and balanced diet.

This educational counseling could be in the form of face-to-face consultation, instructional brochures or through an interdisciplinary approach. Public understanding of the meaning of oral health and its relationship to general health should be encouraged. Finally, fundamental, as well as clinical and population based research, should be carried out to clarify the interaction between oral and general

health. The research findings should then be translated into health care practice and healthy lifestyles. However, changes within the health system to newer therapies is not straightforward because newer therapies are usually more costly. The cost of delivery of health care should not increase the physician's conflict between being a protector of the patient and being a perfect agent for health care policy. Furthermore, in order to assist patients with their health care decision making, their choice of treatment should not be restricted by financial issues.

The graeter patient satisfaction detected from our meta-analysis and similarities between the results of this research project demonstrating the positive impact of mandibular implant overdentures on oral health related quality of life, provide evidence based information for those who shape publicly funded dental treatment. By covering the cost of minimum implant therapy under public health insurance, we can allow the clinician and the patient to chose the best treatment based on their preference and not on the financial issues.

CHAPTER 5

Conclusions

The results of this randomized clinical trial follow-up support the existing evidence of the efficacy of mandibular two-implant overdentures for enhancing and maintaining oral health related quality of life in elders.

These findings suggest that sense of coherence is not a prerequisite for successful management of edentulism. Mandibular two-implant overdentures may maintain the physical perceived health of edentulous elders and may be improve their oral health by controlling denture stomatitis.

Healthy edentulous elders, independent of nocturnal wearing of their dentures, are quite good sleepers. Further studies are needed to evaluate the negative impacts of wearing conventional dentures on sleep quality and daytime sleepiness.

We have highlighted the need to identify and resolve issues of study quality in implant research and recommended that individual patient data be used in future meta-analytic assessments.

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Annex I

Annex II

Inclusion criteria

Male and female
Age 65 years and older
Being edentulous for a minimum of 5 years
Wishing to replace existing conventional dentures
An adequate understanding of written and spoken English or French
Able to understand and respond to the questionnaires used in the study
Willing and able to accept the protocol and to give informed consent

Exclusion criteria

Insufficient bone to place two implants in the anterior mandible (vertical bone height and labio-lingual thickness)
Other oral conditions that preclude immediate prosthetic treatment
Acute or chronic symptoms of temporomandibular disorders
History of radiation therapy to the orofacial region
Systemic or neurologic disease that contraindicate implant surgery, such as uncontrolled diabetes or other metabolic diseases which could affect the normal healing process, uncontrolled hematologic and immunologic diseases and chronic use of systemic steroids. The treatment protocol for patients who are receiving oral or intravenous bisphosphonate therapy is the same as that for general population, expect for the population at risk for bisphosphonate-related osteonecrosis of the jaw (elders, those with ill- fitting prostheses, intra-oral trauma, history of alcohol and/or tobacco use). In such cases, conservative surgical technique, with primary tissue

closure, should be considered.

Surgical procedures

Two root-form titanium implants (ITI Dental Implant, Solid screw SLA implants, Straumann, Waldenburg, Switzerland) were placed in the mandible, anterior to the mental foramina, using the standard surgical protocol recommended by the manufacturer.

Before implantation, none of the patients received any grafts or other treatments to improve the anatomy of the implantation site. For 2 weeks after the implantation procedure, the patients were not allowed to wear their old mandibular dentures. After removal of the sutures, the old denture was adjusted for use.

The denture base was relieved above the healing cap to avoid unfavourable loading of the implant. After verifying occlusion and easy seating of the prosthesis in the mouth, soft relining of the old denture was performed (Trusoft lining material, Harry J. Bosworth Co., Skokie, Ill.).

Annex III

SF-36 HEALTH SURVEY

Date : Identification Code :

		/			/		
a	a		m	m		j	j

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**
O 1	O 2	O 3	O 4	O 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**
O 1	O 2	O 3	O 4	O 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	○ 1	○ 2
b. **Accomplished less** than you would like	○ 1	○ 2
c. Didn't do work or other activities as **carefully** as usual	○ 1	○ 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
○ 1	○ 2	○ 3	○ 4	○ 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
○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> 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 <u>during the past 4 weeks</u>. 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 <u>past 4 weeks</u>:

(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

THANK YOU !

OHIP-20E Questionaire

Identification code :

Date :

a a / m m / d d

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

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

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