Université de Montréal

A randomized controlled trial evaluating
the quality of life and the sense of coherence
in seniors wearing complete conventional dentures
or mandibular two-implant overdentures

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Ce mémoire intitulé:

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a été évalué par un jury composé des personnes suivantes :

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RÉSUMÉ

La supériorité des prothèses mandibulaires retenues par deux implants (IODs) sur les prothèses conventionnelles (CDs) nécessitent d'être éclaircies notamment en rapport à leur influence sur la qualité de vie reliée à la santé bucco-dentaire (OHRQoL) ainsi que sur la stabilité de cet effet de traitement. De plus, l'influence des facteurs psychologiques, tel que le sens de cohérence (SOC), sur l'effet de traitement reste encore inconnue. Le but de cette étude est de déterminer l'amplitude de l'influence du port des IODs et des CDs sur l'OHRQoL et d'évaluer la stabilité de l'effet de traitement dans le temps, tout en prenant en considération le niveau du SOC.

MÉTHODOLOGIE: Des participants édentés (n=172, âge moyen 71, SD = 4.5) ayant reçu des CDs ou des IODs ont été suivis sur une période de deux ans. L'OHRQoL a été évaluée à l'aide du questionnaire « Oral Health Impact Profile (OHIP -20) » et ce avant le traitement et à chacun des deux suivis. Le SOC a été évalué à l'aide du questionnaire « The Orientation to Life (SOC -13) » à chacun des deux suivis. Des analyses statistiques ont été effectuées pour évaluer les différences intra et entre groupes (analyses statistiques descriptives, bivariées et multivariées).

RÉSULTATS: Une amélioration statistiquement significative de l'OHRQoL entre les statuts avant et après traitement a été notée dans les deux groupes (Wilks's Lambda = 0.473, F (1,151) = 157.31, $p < 0.0001$). L'amplitude de l'effet du traitement IOD est 1.5 fois plus grande que celle du traitement CD. Ces résultats ont été stables pendant les deux années d'étude et ils n'ont pas été influencés par le SOC.

CONCLUSION: Le traitement IOD amène une meilleure OHRQoL à long terme en comparaison avec le traitement CD et ce sans influence du niveau du SOC. Ces résultats sont cliniquement significatifs et confirment la supériorité des IODs sur les CDs.

MOTS-CLÉS : étude clinique, qualité de vie, santé orale, sens de cohérence, prothèse totale, implant dentaire.

ABSTRACT

The superiority and stability of the effect of mandibular two-implant retained overdentures (IODs) over conventional dentures (CDs) in relation to the oral health-related quality of life (OHRQoL) remain to be clarified. Furthermore, the influence of psychological factors, such as the sense of coherence (SOC), on the perception of treatment outcomes is still unknown. The aim of this study was to determine the magnitude of the effect of IODs and CDs on the OHRQoL and assess the stability of the treatment over time taking into account the level of SOC.

METHODOLOGY: Edentulous participants (n = 172, mean age 71, SD = 4.5) wearing CDs or IODs were followed up for two years. The OHRQoL was assessed at baseline and both follow-ups using the « Oral Health Impact Profile (OHIP-20) » questionnaire. The SOC was only assessed at both follow-ups using « The Orientation to Life (SOC-13) » questionnaire. Statistical analyses were conducted to evaluate between and within treatment differences (descriptive, bivariate and multivariate statistical analyses).

RESULTS: A significant pre-/post-treatment improvement in the OHRQoL for both treatment groups was found (Wilks's Lambda = 0.473, $F (1,151) = 157.31$, $p < 0.0001$). The magnitude of the effect in the IOD group was 1.5 times larger than that in the CD group. These outcomes were stable over the two-year study period and the SOC did not influence any of these results.

CONCLUSION: IODs provide better long-term OHRQoL than CDs regardless of SOC level. The results are clinically meaningful and confirm the superiority of IODs over CDs.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CD	Conventional denture
CIHR	Canadian Institute of Health Research
ES	Effect size
GOHAI	Geriatric Oral Health Assessment Index
GRR	General resistant resource
HRQoL	Health-related quality of life
IOD	Implant overdenture
ITT	Intention to treat
MID	Minimal important difference
OHIP	Oral Health Impact Profile
OHQoL-UK	United Kingdom Oral Health Quality of Life
OHRQoL	Oral health-related quality of life
OIDP	Oral Impacts on Daily Performances
QoL	Quality of life
SD	Standard deviation
SF -36	Medical Outcomes Short Form 36
SIP	Sickness Impact Profile
SOC	Sense of coherence
SOC -13	The Orientation to Life questionnaire with 13 questions
SPSS	Statistical Package for the Social Sciences
WHO	World Health Organization

Dedication

I dedicate this work to my family, George, Maria and Jaber for all the wonderful moments

and for all the loving support walking the road of life.

ACKNOWLEDGMENTS

It is easy to recognize special people when you meet them. They impress you and they form a deep trace inside you.

I would like to express my sincere thanks to those special people with whom I had the pleasure to meet and work with during my studies at the Université de Montréal, particularly to Dr. Pierre de Grandmont, who generously allowed me to learn from his long experience and to Dr. Elham Emami, who took my hand to grow stronger in research.

I would further like to express my gratitude to Dr. Jocelyne Feine, who always inspired me with the quality of her work, and to Dr. Anne Charbonneau for her continuous support during my studies.

I would like also to recognize the effort of Mr. Pierre Rompé, for his contribution to the statistical analyses and Nicolas Drolet for his assistance in this research.

Finally, I thank the Faculté des études supérieures at the Université de Montréal for supporting me, the Canadian Institute for Health Research (CIHR) for its grant, and the ITI foundation for its participation in this study.

CHAPTER ONE: LITERATURE REVIEW

1.1. Introduction

Maintaining health and quality of life are essential for successful active aging. Access to adequate healthcare and preventive services are important factors for the older population who are at greater risk of suffering from chronic diseases such as edentulism (Health Canada 2002). Health promotion strategies can assure better control over the physical and psychological aspects of health and help the elderly to maintain their autonomy and independence as well as their social performance (Ottawa Charter 1986).

Preserving oral health contributes substantially to the healthy aging process (Public Health Agency 2006). This includes the prevention of oral diseases and the restoration of lost or damaged tissues (Gagliardi *et al.* 2008; Sheiham *et al.* 2001).

Over the last few decades, research on implant technologies and specifically mandibular-implant overdentures has examined the contribution of implant therapy to the quality of life of the elderly population. This has been carried out by analyzing the impact of this type of treatment on the major dimensions of health: physical symptoms, functional capacity, social functioning and perception of well-being (Awad *et al.* 2000a; Heydecke *et al.* 2005b; Hutton *et al.* 2002; Thomason *et al.* 2003). Based on the evidence regarding the positive impact of this technology on the perception of well-being and quality of life, mandibular two-implant retained overdentures (IODs) have been proposed as the standard of care for treating edentulism (Feine *et al.* 2002b; Thomason *et al.* 2009). Although the available evidence points to better patient-based outcomes with this type of treatment, the magnitude

and the stability of the treatment effect is still not clear. Furthermore, little attention has been paid to psychological factors, such as the sense of coherence (SOC), which could interact with the treatment outcomes. Therefore, in order to inform policy makers and the public about their decisions on adoption of implant therapies, it is essential to follow-up healthcare outcomes.

This chapter consists of a review of the literature offering background knowledge on the oral health-related quality of life, sense of coherence and edentulism.

1.2. The oral health-related quality of life

1.2.1. Historical background and definitions

It is difficult to define the term oral health-related quality of life (OHRQoL) without exploring the meaning of health and the quality of life. Both terms existed at least 2500 years ago (Aristotle 384-322 BCE) and received more attention during the second half of the 20th century (Inglehart and Bagramian 2002). Both concepts have been subjected to a lot of debate and have been defined differently by different populations and different users such as clinicians, researchers and health planners (McDowell and Newell 1996). Although both terms mean distinct constructs, they have been used interchangeably in the literature and many definitions have attempted to link the two of them (Spilker 1991).

The World Health Organization (1948) has defined health as *"the state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity"*. The World Health Organization Quality of Life Group (1995) defined the quality of life as *"an individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"*. This definition points out the multidimensional and subjective character of the quality of life.

Health-related quality of life (HRQoL) has emerged to describe the social, emotional, and physiological well-being following a treatment (Greer 1984) and to assign value to life as modified by disability or impairment (Locker 1998). It was argued that health-related

quality of life should not reflect only a disease- or treatment-related status but should also be seen in terms of its multidimensional, dynamic and subjective nature and in relation to the outcomes of health conditions (Allison *et al.* 1998; Efficace and Bottomley 2003; Gill and Feinstein 1994).

The oral health-related quality of life (OHRQoL) construct is similar to that of health-related quality of life (Gift *et al.* 1997). The Surgeon General Report on oral health (2000) proposed that the term should reflect people's functional and psychological perception of their oral conditions. Consequently, the term was defined in the report as a *"multidimensional construct that reflects people's comfort when eating, sleeping and engaging in social interaction, their self-esteem and their satisfaction with respect to their oral health"*. Other definitions have also been suggested in the literature such as *"the impact of oral conditions on the quality of life"* (Slade and Spencer 1994a) and *"the extent to which oral disorders affect the functioning and psychosocial well-being"* (Locker *et al.* 2000).

1.2.2. The relation between oral health, general health and quality of life

The relation between oral health, general health and quality of life is reciprocal and takes into consideration the interaction between the oral cavity and the rest of the body. Oral health does not only mean the absence of oral diseases but reflects the complete functional, social and psychological well-being (Akifusa *et al.* 2005; Gift and Atchison 1995; Locker

1997). The overall general health and quality of life can be negatively influenced by compromised oral health (Akifusa *et al.* 2005; Gift and Atchison 1995).

There is overwhelming evidence of the negative effect of poor oral health on general health, quality of life, social life and day-to-day activities. The direct impact of dental status on obesity, weight loss, nutrition, and diet has been reported in several studies (Krall *et al.* 1998; Saito *et al.* 2001; Yoshihara *et al.* 2009). In a three-year longitudinal study of 638 veterans, Krall *et al.* (1998) found that fiber, calorie and vitamin intake decreases significantly with the progressive loss of teeth regardless of gender or age. Yoshihara *et al.* (2009) longitudinally evaluated the association between the number of remaining teeth and the quality of diet intake in 57 elderly adults. According to this study, individuals with 19 teeth or less have significantly lower protein, vitamin, niacin, and pantothenic acid intake than individuals retaining 20 teeth or more.

McGrath and Bedi (1999) highlighted the importance of the interaction of oral conditions with daily physical, psychological and social functions. They reported that men were more concerned about the physical aspects of oral health including eating and chewing whereas women were more disturbed with psychological dimensions such as self-confidence. Using national survey data in the United Kingdom, the same authors (2002) suggested that the deterioration of quality of life in the elderly is due to the accumulation of oral disorders and the decline in oral functions. They demonstrated that the number of remaining teeth is an important determinant of the oral health-related quality of life (OHRQoL) and proposed that maintaining 20 teeth or more should be considered a predictor of good oral health.

Studies on the Canadian population (Locker 2001) revealed that 6 to 9% of Canadians experience moderate to severe dental pain that interrupts their daily activities. Thirteen percent of Canadians reported chewing problems and 10% had speaking problems that affected the perception of their well-being. In a 32-year longitudinal study of 708 male participants, an association was found between chronic endodontic inflammation and coronary heart disease (Caplan *et al.* 2006). In addition, Pihlstrom *et al.* (2005) reported in a systematic review an association between periodontal diseases and negative pregnancy outcome, cardiovascular diseases, stork, pulmonary diseases, and diabetes.

Oral health and oral health-related quality of life (OHRQoL) have an important impact on both the individual and the community health level. At the individual level, it provides a better understanding of the effect of oral conditions on individuals' quality of life. Furthermore, it allows clinicians to evaluate the quality of care and compare the outcomes of different interventions (Eklund and Burt 2002; Locker 1995). At the community level, the OHRQoL provides a better assessment of population needs. It may assist in planning new healthcare policies and improving public health services (Sheiham *et al.* 1982; Weintraub 1998).

1.2.3. Oral health-related quality of life in the elderly

Geriatric dentistry is "*the branch of dental care involving problems peculiar to advanced age and aging*" (Glossary of prosthodontic terms 2005). This field is becoming more and more important as all nations are experiencing growth in their elderly population (Douglass

et al. 2002). In Canada, it was estimated that there would be a 36.5% increase in the number of people aged 65 and over by the year 2012 (Thompson and Kreisel 1998).

A variety of factors have been identified as predictors of the oral health-related quality of life (OHRQoL) in the elderly population. These factors include: comfort, the ability to eat, lack of pain and a healthy mouth (MacEntee *et al.* 1997). In a cross-sectional study, Locker *et al.* (2002) evaluated the impact of oral conditions on the quality of life of 225 seniors with different medical conditions. According to their results, more than half of the subjects experienced psychological or functional problems due to poor oral health. They complained of missing teeth, chewing limitations, and dry mouths. They also reported that their poor oral health could lead to a stressful life pattern and low perception of life satisfaction. Consequently, the authors concluded that improving the oral health may improve the quality of life of the elderly population.

Smith and Sheiham (1979) conducted structured interviews to determine how oral conditions can affect elderly activities. They reported that social embarrassment related to the time needed to finish a meal, eating in front of others, and being uncomfortable during social contacts could affect daily activities.

In an international survey conducted in Australia, the United States and Canada, Slade *et al.* (1996) evaluated the social impact of oral conditions on quality of life in the elderly. Their findings showed that individuals assess their oral health-related quality of life (OHRQoL) differently depending on social and cultural diversity. In this study, seniors suffering from missing teeth, root decay, root fragments and periodontal pockets were more socially affected than the other groups with better oral health. In addition, more negative social

impact was perceived in edentulous individuals or subjects reporting irregular dental visits than in dentate individuals or those visiting their dentists regularly.

1.2.4. Measuring the oral health-related quality of life

The importance of the oral health-related quality of life (OHRQoL) assessment is based on different aspects. The assessment allows populations with different oral conditions to be quantified, analyzed, and compared using the same scale (Slade and Spencer 1994a). The information provided by these measures facilitates the understanding and the translation of the individuals' needs. Furthermore, the use of this measurements with clinical data enables evaluation of the improvement or the responsiveness of a particular treatment and comparison with other alternatives (Allen 2003). Finally, this assessment may assist researchers and policymakers to define goals, to plan oral healthcare programs, to provide funds for such healthcare programs, and to compare what is established with what was planned in order to achieve optimal oral healthcare services (Allen 2003; Slade and Spencer 1994a) .

To assess the oral health-related quality of life (OHRQoL) two types of instruments could be used: generic and disease-specific instruments. Generic instruments are designed to measure a broad range of conditions, since they focus on overall well-being (Fletcher *et al.* 1992). The Sickness Impact Profile (SIP) and Medical Outcomes Short Form 36 (SF-36) are two examples of the generic instruments.

Another advantage of these instruments is that their psychometric properties allow the comparison between different individuals with different problems, and thus they are suitable to be used across different populations. The major disadvantage of the generic instruments is their lack of sensitivity and responsiveness. This is especially important in the assessment of specific disorders such as arthritis, or oral diseases (Allen *et al.* 1999; Fletcher *et al.* 1992) .

Disease-specific measurements are designed to focus on particular health conditions or populations. These measurements have better sensitivity and responsiveness than generic instruments. Therefore, they are more likely to detect minor changes toward the targeted conditions. However, they are less suitable when comparing different populations. Disease-specific instruments are useful for the evaluation of particular disorders such as cancer therapy or oral disease outcomes including the effect of tooth loss (Allen 2003; Allen *et al.* 1999; Fletcher *et al.* 1992).

Different types of oral disease-specific measurements have been introduced and validated (Adulyanon *et al.* 1996; Atchison and Dolan 1990; Benyamini *et al.* 2004; Grath *et al.* 2000; McGrath and Bedi 2001; Slade and Spencer 1994a). One of these instruments is the Geriatric Oral Health Assessment Index (GOHAI), which allows the evaluation of the impact of oral disorders on health-related quality of life in the elderly (Atchison and Dolan 1990). Another instrument is the Oral Impacts on Daily Performances (OIDP), which attempts to quantify the frequency and the severity of impacts of oral problems on daily activities (Adulyanon *et al.* 1996). The United Kingdom Oral Health Quality of Life (OHQoL-UK) questionnaire was developed to reflect public views on key areas that

influence the oral health-related quality of life (Grath *et al.* 2000; McGrath and Bedi 2001). The Self-Rated Oral Health (SROH) questionnaire was designed to measures the subject's overall assessment of his or her oral health (Benyamini *et al.* 2004). Finally, one of the most widely used instruments and perhaps the most sophisticated, is the Oral Health Impact Profile (OHIP).

1.2.4.1. The Oral Health Impact Profile

The Oral Health Impact Profile (OHIP) was developed by Slade and Spencer (1994a). This instrument is a self-administrated disease-specific measurement that assesses patients' perception of the physical, psychological, and social impacts of oral health on their well-being. The original version (OHIP-49) contains 49 questions divided into seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. These dimensions are based on the theoretical framework of health (WHO 1980). This questionnaire has been tested for its discriminant, concurrent and predictive validity, internal consistency, sensitivity, and responsiveness, as well as its reliability (Allen and Locker 1997; Rener-Sitar *et al.* 2008; Slade and Spencer 1994a; Slade *et al.* 1996). Cultural and language adaptations have also been made for the OHIP (Al-Jundi *et al.* 2007; Allison *et al.* 1999; Bae *et al.* 2007; Barer *et al.* 2007; Ekanayake and Perera 2003; Fernandes *et al.* 2006; Ide *et al.* 2006; John *et al.* 2002; Kushnir *et al.* 2004; Larsson *et al.* 2004; Montero-Martin *et al.* 2009; Saub *et al.* 2005; Souza *et al.* 2007; van der Meulen *et al.* 2008; Wong *et al.* 2002).

The major disadvantage of using the OHIP-49 questionnaire is the large number of statements that make it difficult to use in usual clinical situations (Allen and Locker 2002). To overcome this limitation, a shorter version (OHIP-14) that contains 14 questions for dentate people was developed and tested for its validity and reliability (Slade 1997). However, this version does not contain items for edentate people and the decreased number of questions was thought to affect its responsiveness to minor changes (Allen and Locker 2002).

Consequently, a newer version, OHIP-20, was developed to meet the requirements for completely edentulous patients (Allen and Locker 2002). This version was tested for its reliability, validity and responsiveness (Allen and Locker 2002; Locker and Allen 2002). The questionnaire has 20 items: Three items for functional limitation, four items for physical pain, two items for psychological discomfort, four items for physical disability, two items for psychological disability, three items for social disability and two items for handicap. These items are rated on six-point Likert-type scales (1=never; 2-rarely, 3=occasionally, 4=often, 5=very often and 6=all of the time). The total score of the scale ranges between 20–120 points, with lower scores indicating better oral health-related quality of life (OHRQoL) (Allen and Locker 2002; Slade and Spencer 1994a). Two validated methods were described in the literature for calculating the total OHIP score: either by simply summing up the reported negative impacts, or by adding up the statement scores (Allen and Locker 1997).

1.3. The sense of coherence

1.3.1. Historical background and definition

In 1979, Aaron Antonovsky conducted an epidemiological study to evaluate the effect of menopause in Israeli women. Surprisingly, he found that 29% of women had survived the concentration camps and maintained their health and well-being in spite of the events of the Second World War. He remarked that these women shared the same psychological characteristics, which he termed the sense of coherence (SOC). These characteristics made them more resilient to life stressors (Antonovsky 1979; Antonovsky 1987). Later, he developed his theory of health and illness or « salutogenesis » and defined the SOC as: *"A global orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence that: 1- the stimuli deriving from one's internal and external environments in the course of living are structured, predictable and explicable; 2- the resources are available to one to meet the demands posed by the stimuli; and 3- these demands are challenges, worthy of investment and engagement"* (Antonovsky 1987).

In addition, Antonovesky determined three core components for the sense of coherence (SOC): Comprehensibility, Manageability and Meaningfulness.

1. Comprehensibility (The cognitive component): *"The extent to which one perceives the stimuli that confront one, deriving from the internal and external environments, as making cognitive sense, as information that is ordered and structured rather than a noise – chaotic accidental and inexplicable".*

2. Manageability (The instrumental and behavioral component): *"The extent to which one perceives that resources are at one's disposal, which are adequate to meet the demands posed by the stimuli that bombard one"*.

3. Meaningfulness (The motivational component): *"The extent to which one feels that life makes sense emotionally, that some of the living events are worth investing energy, commitment and engagement"*.

A person with a strong sense of coherence (SOC) copes better in response to environmental stressors than a person with a weak SOC (Antonovsky 1979; Antonovsky 1987; Eriksson and Lindstrom 2006; Eriksson and Lindstrom 2007; Suominen *et al.* 2001). A strong SOC enables individuals to find the appropriate resources to overcome the stimuli and to better react in stressful situations. In addition, individuals with a strong SOC look at difficult situations as meaningful challenges and worthy experiences. A person with a strong SOC is more likely to maintain health and well-being even under strenuous life events. According to a systematic review by Eriksson and Lindstrom (2006), there is a high correlation between the SOC and other psychological concepts such as optimism, hardiness, anxiety and acceptance of disability. Furthermore, these authors found that SOC correlates positively with optimism and self-esteem and negatively with depression and anxiety.

1.3.2. The salutogenic model

In contrast to the pathogenic model, which concentrates on specific pathogens or stressors that make people ill, the salutogenic model focuses on resources that promote people's health and protect them from disease or sickness (Antonovsky 1979; Antonovsky 1987). The salutogenic model emphasizes the relationship between health, stress and coping. In this approach, researchers attempt to find the answer to this question: Why do some people, regardless of major stressful situations and severe handicaps, stay healthy while others do not?

The salutogenic approach is based on two components: the sense of coherence (SOC) as the core component and the general resistant resources (GRRs), which have been defined as "*each characteristic of a person, a group, or an environment that can facilitate effective tension management*". Typical GRRs are knowledge, experience, self-esteem, money, and intelligence (Antonovsky 1979; Antonovsky 1987). It was suggested that psycho-emotional resources are more important than socio-economic resources and that factors such as social and partner's support, the quality of work, and the childhood living conditions were the most important factors (Volanen *et al.* 2004).

The salutogenic approach is not limited to the individual level, but it can be applied to general public health (Eriksson and Lindstrom 2008). According to the Ottawa Charter (1986), a public health plan should be based on health promotion strategies. The salutogenic approach meets the Ottawa Charter statements by promoting people's health

and well-being through strengthening cultural, social and behavioral attitudes (Eriksson and Lindstrom 2008).

1.3.3. Development, dynamism and stability over the lifespan

The sense of coherence (SOC) starts its evolution as soon as a child is born. During adolescence and adulthood, the influence of environmental variables and life stressors lead to a strong or weak SOC. According to Antonovsky's theory, by the age of 30, a person has already been exposed to a broad pattern of life experiences. His SOC reaches its maturity and becomes relatively stable (Antonovsky 1979; Antonovsky 1987; Antonovsky and Sagy 1986). A person who has developed a strong SOC copes well with life stressors and his strong SOC continues to crystallize, whereas in a person with a weak SOC, life is transformed into a vicious, unmanageable, and meaningless cycle.

There is controversy in the literature in relation to the stability of the sense of coherence (SOC).

Several studies have demonstrated that sense of coherence (SOC) is stable over the lifespan (Eriksson and Lindstrom 2005; Kuuppelomaki and Utriainen 2003; Nilsson *et al.* 2003; Suominen *et al.* 2001). In a three-year longitudinal study in healthcare students, Kuuppelomaki and Utriainen (2003) showed that almost all individuals with a strong SOC at baseline maintain or strengthen their SOC level regardless of the surrounding environmental variables. Suominen *et al.* (2001) analyzed the stability of the SOC in a four-year study with 1976 randomly selected participants. Their results revealed that the average

SOC scores remained stable during the study period with no variation between women and men.

In contrast, some studies have questioned the stability of sense of coherence (SOC) and suggested that negative life events tend to decrease the level of SOC (Smith *et al.* 2003; Snekkevik *et al.* 2003; Volanen *et al.* 2007). The more severe and recent the negative event, the more likely it will influence the level of SOC regardless of gender or age (Volanen *et al.* 2007). Nilsson *et al.* (2003) used data from two national surveys in 1994 and 1999 and found that the overall SOC decreased over time except for individuals with an initially strong SOC. In a longitudinal study, the stability of the SOC was investigated in individuals who had experienced severe physical trauma (Snekkevik *et al.* 2003). The level of SOC was measured at admission, at discharge from hospital and at a one to three-year follow-up. The results of this study indicated that the SOC level is unstable and is not predictable over a period of time. According to Smith *et al*. (2003), environmental factors and work conditions stressed the individuals even after the age of 30, and decreased the level of their SOC.

According to a recent systematic review (Eriksson and Lindstrom 2005), it was concluded that sense of coherence (SOC) tends to increase with age partially because of personal development or staying healthy with men ranking their SOC higher than women. However, the authors also mention that subjects with initial high SOC seems to maintain a comparatively stable level over time. No reason was given to explain this characteristic.

As shown, some studies have reported that the sense of coherence (SOC) is stable whereas others have reported the opposite. As a result, the issue of whether the SOC remains stable over time is still not clear.

1.3.4. Sense of coherence assessment

The sense of coherence (SOC), like all psychological aspects, is difficult to measure. In addition, the overlap with other concepts, such as optimism and anxiety, add to this complexity (Carmel and Bernstein 1989; Eriksson and Lindstrom 2006). The SOC is measured using The Orientation to Life questionnaire introduced by Antonovsky (1987). Several versions have been developed for different populations such as for families (Hoehn-Anderson 1998), children (Sagy and Dotan 2001), and adolescents (Bowen *et al.* 1998).

The original version (Antonovsky 1987) consists of 29 items that cover three domains: Comprehensibility, Manageability and Meaningfulness. A shortened version that contains 13 items was also developed to facilitate the clinical use. It consists of five items for Comprehensibility, four items for Manageability, and four items for Meaningfulness (Antonovsky 1987). Both the original and the shortened versions were tested for their validity, reliability and responsiveness (Antonovsky 1987; Antonovsky 1993; Feldt *et al.* 2007; Flannery *et al.* 1994). According to Antonovsky (1993), the questionnaires should be used to assess the SOC concept globally and not individually. He claims that such assessment could be misleading and could lead to inappropriate interpretations.

Each item is rated on a seven-point Likert-type scale, with two anchoring responses "never or very seldom" and "always or very often". The total score is obtained by adding up the individual raw scores. For the shortened version, the total score ranges from 13 to 91. Five of the items are negatively stated and reversed in scoring so that higher scores indicate a stronger SOC, and in a similar way, a lower score indicates a weaker SOC (Antonovsky 1987). According to categorization based on tertile values, SOC scores can be considered as strong (66–91), moderate (39–65) or poor SOC (13–38) (Kattainen *et al.* 2006; Statistics Canada 1995; Stephens *et al.* 1999).

1.3.5. The relation between the sense of coherence, health and quality of life

The salutogenic model and the sense of coherence (SOC) were introduced as psychological factors that play a positive role in maintaining health and promoting healthy behaviors (Antonovsky 1987).

Many studies have been conducted to investigate the relation between the sense of coherence (SOC), health and quality of life (QoL). In a systematic review by Eriksson and Lindstrom (2006) the association between SOC and health, especially mental health, was demonstrated. A person with a strong SOC is able to cope well with environmental stressors resulting in perception of better health and health-related quality of life (HRQoL). A high positive correlation was found between SOC and other psychological aspects such as optimism, hardiness, learned resourcefulness, self-esteem, efficacy, and acceptance of

disability (Carstens and Spangenberg 1997; Kravetz *et al.* 1993; Lundberg and Peck 1994; Matsuura *et al.* 2003; Skirka 2000; von Bothmer and Fridlund 2003). In addition, the SOC was considered as an internal complementary resource that contributes to a person's state of health (Suominen *et al.* 2001). It was suggested that people with a high SOC have fewer health problems than those with a weak SOC. For example, a strong SOC was found to be associated with increased oxygen uptake, lower diastolic blood pressure, lower serum triglycerides, and lower heart rate at rest (Kouvonen *et al.* 2008; Lundberg and Peck 1994; Poppius *et al.* 1999).

In addition, it is also reported that a strong association exists between the sense of coherence (SOC) and quality of life (QoL) (Eriksson and Lindstrom 2007). Regardless of the study population or the study design, individuals with a strong SOC perceived their QoL to be better compared to those with a weak SOC.

1.3.6. The relation between the sense of coherence and oral health-related quality of life

Recently, the salutogenic approach has been used to understand factors that influence oral health and oral health behaviors. Savolainen *et al.* (2005a) carried out a national survey and investigated the relation between socio-economic factors, the oral health-related quality of life (OHRQoL) and the sense of coherence (SOC). Their results suggested that dentate adults with a strong or moderate SOC have a significantly better OHRQoL than those with a weak SOC. The authors concluded that the SOC seems to be a determinant of the

OHRQoL independently of the other variables. In a cross-sectional study, the same research group (2005b) tested the relation between the SOC and oral health-related behavior including the quality and frequency of tooth brushing in a sample of adolescent dentate participants. Their results suggest that subjects with a lower SOC had worse oral hygiene and brushed their teeth less frequently.

Sense of coherence (SOC) may increase subjects' awareness of their oral health (Freire *et al.* 2001). In a cross-sectional study, adolescents with a high SOC were more likely to visit their dentists for check-ups than those with a low SOC. Accordingly; the authors concluded that the SOC may be a psychological determinant of oral health as it positively affects the pattern and frequency of dental attendance.

In a survey of 970 adolescents (between 12 and 19 years old), Ayo-Yusuf *et al.* (2008) demonstrated an association between self-reported gingivitis and the sense of coherence (SOC). The authors concluded that the SOC is an independent risk factor for poor gingival health. The results of these studies should be interpreted with caution given the fact that oral health behavior in adolescents may be influenced by their parents' behavior, and that the reliability of self-reported gingivitis is questionable.

The association between the oral health-related quality of life (OHRQoL) and the sense of coherence (SOC) has also been investigated in edentulous elderly individuals (Emami *et al.* 2009a). According to this study, the OHRQoL of edentulous individuals was improved by the effect of the type of prosthetic treatment regardless of the SOC level.

Studies focusing on the correlation between the sense of coherence (SOC) and the oral health-related quality of life (OHRQoL) are limited and their results are controversial. Therefore, there is still a need to clarify the role of SOC in improving the quality of life in the context of oral conditions and oral diseases.

1.4. Edentulism

1.4.1. Definition and epidemiology

Edentulism is *"the state of being edentulous; without natural teeth"* (Glossary of prosthodontic terms 2005).

The prevalence of complete edentulism varies greatly between countries (Table 1) (Petersen *et al.* 2005). In Canada, the prevalence has significantly declined since 1990. In 2003, 9% of the population were edentulous compared to 16% in 1990 (Millar and Locker 2005) . Although the province of Quebec has witnessed the highest reduction of prevalence of complete edentulism, from 1990 to 2003 (from 28% to 14%) (Brodeur *et al.* 1996; Millar and Locker 2005), its prevalence is still the highest in Canada followed closely by Newfoundland, New Brunswick and Saskatchewan (Table 2) (Millar and Locker 2005).

Several factors have been reported to be associated with edentulism such as age, gender, education, socio-economic factors and access to dental care. The prevalence of edentulism increases with age. In 2003, almost one third of Canadian elderly were completely edentulous (Millar and Locker 2005) (Figure 1). In addition, the prevalence of edentulism was higher in women for all age groups (Brodeur *et al.* 1996; Millar and Locker 2005) (Figure 2). Although there is no scientific explanation for this gender difference, it could be attributed to oral health behaviors such as seeking for aesthetics or rating of health perception (Pan *et al.* 2008). Furthermore, it was estimated that the prevalence of edentulism is six times higher in individuals with a lower educational level than in those

with a higher educational level (Brodeur *et al.* 1996). Moreover, edentulism is more prevalent in rural areas with limited dental services (Vargas *et al.* 2002) and among people with lower incomes (Millar and Locker 1999; Millar and Locker 2005). Finally, unhealthy behaviors such as smoking or poor oral hygiene can lead to edentulism (Beltran-Aguilar *et al.* 2005; Millar and Locker 2007).

Table 1: Prevalence of complete edentulism in the elder population (65 years and older).

Source: From WHO Oral Health Country/Area Profile Program database and Petersen *et al* (2005).

WHO region Country	Year	Edentulous (%)	Age group (year)
The Americas			
Canada	1993	58	65+
USA	1999-2004	26	65–69
Asia			
Sri Lanka	1994-1995	37	65–74
China	1995-1996	11	65–74
Malaysia	2000	57	65+
Europe			
Albania	1996	69	65+
Austria	1992	15	65–74
Bosnia and Herzegovina	1998	78	65+
Denmark	2000	27	65–74
UK	1998	46	65+
Africa			
Gambia	1995	6	65+
Nigeria	1998-1999	1.3	65+

Table 2: The prevalence of complete edentulism in Canada by province, 2003.
Source: 2003 Canadian Community Health Survey (Millar and Locker 2005).

Percentage of household population aged 15 or older who were edentate, 2003.	
Quebec	14
Newfoundland and Labrador	13
New Brunswick	12
Saskatchewan	12
Nova Scotia	10
Alberta	7
British Columbia	7
Manitoba	7
Nunavut	7
Prince Edward Island	7
Yukon	7
Ontario	6
Northwest Territories	5
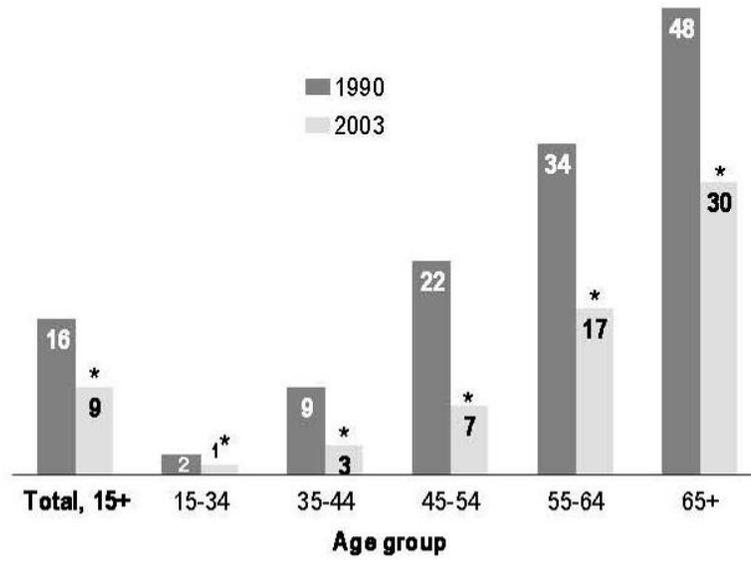
Figure 1: Percentage of complete edentulism in Canada by age group, 1990 and 2003.
Source (Millar and Locker 2005).
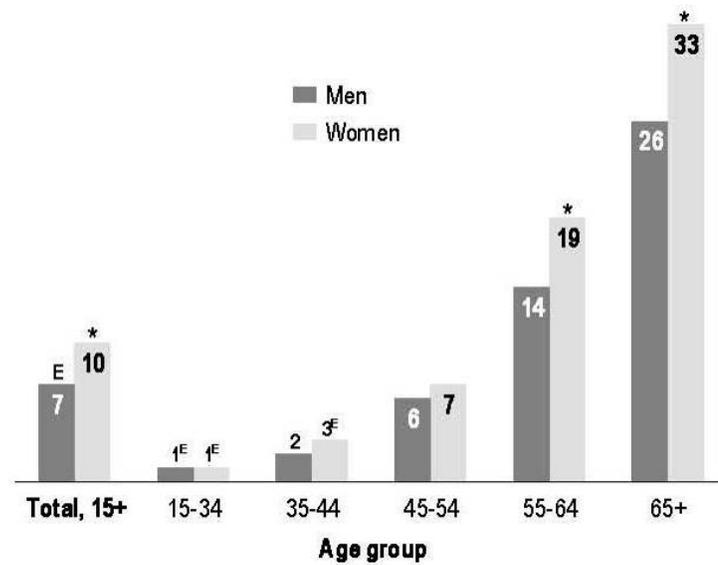
Figure 2: Percentage of compete edentulism in Canada by age group and gender, 2003.
Source (Millar and Locker 2005).

1.4.2. The anatomical, functional and psychological impact of edentulism

The negative effects of edentulism are well documented. Following tooth loss, a decrease in the height and in the width of the alveolar bone begins and continues throughout life (Bergman and Carlsson 1985; Tallgren 1972). Bone loss is four times more severe in the mandible than in the maxilla and this is suggested to be related to anatomic, metabolic and functional factors (Atwood 2001). This resorption leads to a decrease in the denture-bearing area and problems in denture stability (Devlin and Ferguson 1991). The mucosa becomes thin and fragile (Budtz-Jorgensen 1981). The "dished in" appearance results from a decrease in the lower face height, which leads to chin prominence and to a pseudo class III jaw relationship (Carlsson and Persson 1967; Tallgren 1969).

The effect of edentulism on masticatory function has been widely reported. The chewing ability of completely edentulous individuals wearing conventional dentures (CDs) is significantly decreased (Osterberg *et al.* 1996; Wayler and Chauncey 1983). In addition, several studies have estimated that the maximum bite force in edentulous people is five times less than that in their dentate counterparts (Haraldson *et al.* 1979; Helkimo *et al.* 1977). Furthermore, masticatory performance and chewing strokes are significantly reduced in edentate patients (Heath 1982). People wearing CDs have more difficulty chewing hard food than dentate subjects (Wayler and Chauncey 1983). Nutritional studies have shown that poor quality diet is associated with wearing CDs (Osterberg and Steen 1982). Edentulous people are more likely to suffer from malnutrition (Makhija *et al.* 2007), compromised nutritional intake (Morais *et al.* 2003), lack of specific nutrients (Ranta *et al.*

1988), and are at risk for various health problems such as involuntary weight loss (Hutton *et al.* 2002).

Teeth loss may have a profound impact on psychosocial well-being and can lead to serious psychological problems (Fiske *et al.* 1998). Edentulous people try to hide their tooth loss and they report the influence of tooth loss on their daily activities such as at work, during social activities and sexual behavior (Davis *et al.* 2000; Heydecke *et al.* 2005b). High numbers of edentulous individuals are unable to cope with their oral conditions and are considered as "maladaptive". These individuals have low self-confidence, premature aging, altered self-image and altered behavior when socializing and forming close relationships (Friedman *et al.* 1987; Friedman *et al.* 1988a; Friedman *et al.* 1988b).

1.4.3. The impact of edentulism on the oral health-related quality of life

Quality of life is partly affected by a person's oral health (Allen 2003). Edentulism negatively influences oral function, social life and individual's daily activities. Based on Locker's theoretical framework of oral health (Figure 3), tooth loss is an anatomical impairment which leads to pain and discomfort during chewing and eating (Locker 1988). Edentulism could restrict the performance of daily activities such as food mastication. Edentulous people are less comfortable eating with others and are embarrassed by the need for additional time to finish their meals (Smith and Sheiham 1979). In addition, edentulism is related to the inability to talk or smile and the restriction of social activities (McMillan and Wong 2004; Slade and Spencer 1994b). Most edentulous patients feel hopeless and

believe they have to accept denture problems as part of being edentulous (Davis *et al.* 2000; MacEntee *et al.* 1997). All of these constraints can lead to disability. In addition some edentulous individuals could be considered as handicapped if their social embarrassment and isolation prevent them participating in normal life activities (Figure 3) (Locker 1988).

In a survey of 249 edentulous individuals, more than half suffered from physical pain and one third reported reduced well-being. To overcome these unfavorable conditions they adopted different coping strategies, such as denial and disengagement, which are negative predictors of the quality of life (Heydecke *et al.* 2004).

Consequently, edentulism is a major indicator of poor oral health-related quality of life (OHRQoL). These overwhelming evidences and others (Allen and McMillan 1999; Awad *et al.* 2003b; Gagliardi *et al.* 2008; Locker *et al.* 2002; Strassburger *et al.* 2004; Strassburger *et al.* 2006; Strauss and Hunt 1993) show the negative effect of complete tooth loss on the perception of quality of life in the context of oral conditions.
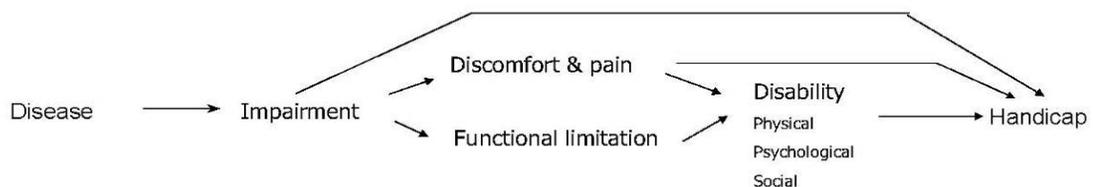
Figure 3: Conceptual model for measuring oral health.
Source: (Locker 1988)

1.4.4. Treatment for edentulism

Prosthetic treatment of completely edentulous patients consists of either conventional dentures or implant supported or retained overdentures (Zarb *et al.* 2004).

Replacing missing teeth with conventional dentures (CDs) is still the most common treatment for edentulism. The support, retention and stability of CDs are obtained from the residual bone ridge underneath (Tallgren 1972). However, these are limited by the ridge morphology and the patient's adaptation. Most edentulous individuals complain about their mandibular prosthesis. This may be due to many factors such as extensive mandibular bone resorption, the form of the mandibular arch, and the presence of the tongue (Atwood 1971; Tallgren 1972; Zarb *et al.* 2004).

With the high success rate of dental implant therapy (Zarb *et al.* 2004; Zarb and Zarb 1985), mandibular two-implant retained overdentures (IODs) have been suggested as a cost-effective treatment for overcoming the limitations of the lower conventional dentures (CDs) (Heydecke *et al.* 2005a). In this design, two implants are placed in the anterior region of the mandible and the prosthesis obtains its support from both implants and the alveolar ridge. Because of its simplicity and the minimal number of implants, the initial cost is relatively low in comparison to other implant treatment alternatives. Different types of abutment design and retentive system (bar, ball, magnetic) are available for the supra-structure prosthesis (Shafie 2007).

1.4.4.1. Advantages of mandibular two-implant retained overdentures

The superiority of the mandibular two-implant retained overdentures (IODs) over conventional dentures (CDs) has been shown in different studies. Laboratory tests have demonstrated a significant improvement in the chewing ability, an almost two-fold increase in the maximum bite force, and a significant reduction in the chewing cycles of individuals wearing IODs compared to those wearing CDs (Bakke *et al.* 2002; Cune *et al.* 2005; van der Bilt *et al.* 2006).

Many randomized controlled trials (RCTs) have reported the positive impact of IODs on patients' general health, satisfaction and oral health-related quality of life (OHRQoL). Individuals wearing IODs indicated an enhancement in their nutritional intake and food selection. They demonstrated improvement in serum nutrients and anthropometric measures such as better fat distribution, and an increase in serum albumin and hemoglobin (Morais *et al.* 2003). In addition, they reported a significant improvement with regards to comfort, stability of their prosthesis, speech, aesthetics, and ability to clean their dentures (Allen and McMillan 2002; Awad *et al.* 2003a). It was reported that individuals wearing IODs had few problems with their oral functions, a high level of satisfaction, and a high level of OHRQoL (Awad *et al.* 2003b). With time, patients' satisfaction with their prostheses increased for the IOD wearers whereas it decreased for CD wearers (Raghoebar *et al.* 2000; Raghoebar *et al.* 2003). Recently, IODs were suggested as the standard of care for treating the mandible of edentulous individuals (Feine *et al.* 2002a; Thomason *et al.* 2009).

The cost-effectiveness of IODs has been assessed in different studies (Heydecke *et al.* 2005a; Stoker *et al.* 2007; Visser *et al.* 2006). Heydecke *et al.* (2005a) used a disease-specific OHRQoL index, together with resource-based micro-costing of treatment, to assess the cost-effectiveness of IODs. They found that IODs improved the OHRQoL by 33%, with an additional expense of $CAN 1593 compared to CDs. This value was translated into a yearly additional cost of $14.41 per improvement point on the Oral Health Impact Profile (OHIP-20) scale (Heydecke *et al.* 2005a). For IODs, the total overall cost was found to be 1.8 times the cost of CDs (Takanashi *et al.* 2004).

CHAPTER TWO: PROBLEMATIC, HYPOTHESES, RESEARCH AIM AND METHODOLOGY

2.1. Problematic, hypotheses and research aim

2.1.1. Problematic

There is still controversy regarding the superiority of the mandibular two-implant retained overdentures (IODs) over the conventional complete dentures (CDs) in terms of oral health-related quality of life (OHRQoL) and the magnitude of the effect remains uncertain (Allen and McMillan 2002; Allen *et al.* 2006; Awad *et al.* 2003b; Emami *et al.* 2009; Heydecke *et al.* 2003). Furthermore, it is unclear whether the treatment effect will stay stable overtime. In addition, less attention has been paid to the psychological factors, such as the sense of coherence (SOC), that could interact with the treatment perception. Thus, longitudinal studies are needed to better assess the long-term outcomes of randomized controlled clinical trials (RCTs). Feine *et al.* have carried out an RCT to compare the nutritional health of edentulous elders wearing IODs and CDs (Emami *et al.* 2008; Pan *et al.* 2008; Perri *et al.* 2006). This longitudinal project aims to follow this cohort of participants to determine whether IOD treatment improves the OHRQoL of elderly edentulous people. This master's degree project reports the results of the two-year follow-up.

2.1.2. Hypotheses

We tested the null hypotheses that:

1. There is no difference in the treatment effect on the oral health-related quality of life of edentulous individuals who wear mandibular two-implant retained overdentures with individual ball attachments and those who wear conventional dentures.

2. The treatment effect of these two interventions on the oral health-related quality of life of edentulous individuals is not stable over time.

3. The sense of coherence is not stable over time and it does not influence the treatment outcome.

2.1.3. Research aim

Primary objectives

To compare the impact of mandibular two-implant retained overdentures and conventional dentures on seniors' oral health-related quality of life two years after they have received their new prostheses and assess the stability of the treatment effect.

Secondary objectives

To assess the stability of the sense of coherence and its association with the oral health-related quality of life.

2.2. Methodology

The sample population was composed of 255 edentulous participants (men and women, 65 years and over) who were enrolled in a randomized controlled clinical trial (RCT). This RCT, approved by McGill University Institutional Review Boards, was to assess the impact of mandibular two-implant retained overdentures on nutritional status, diet and general health.

Participants who met the inclusion criteria (Table 1) were initially randomized into two groups and received either mandibular overdentures retained by ball attachments on two implants (ITI, Straumann, Waldenburg, Switzerland) (IODs) or conventional dentures (CDs), both opposed by new conventional maxillary dentures. Standard surgical and prosthodontic procedures were followed, as in previous RCTs undertaken by this research group. Nutritional state, general health and oral health-related quality of life (OHRQoL) of all participants were measured at baseline, at six months and one year following delivery of the prostheses. After the six-month follow-up, it was planned to follow this cohort for two, five, ten and fifteen years. Therefore, after being informed about this follow-up study, each patient who agreed to participate was asked to sign written informed consent approved by the McGill and the Université de Montréal Institutional Review Boards.

The study outcome was the oral health-related quality of life (OHRQoL). The Oral Health Impact Profile (OHIP-20) questionnaire was used to measure the OHRQoL at baseline, one and two years following delivery of the new prostheses. This validated

questionnaire consists of 20 items that can be answered on six-point Likert-scale. The total range of the scale is 20-120 points with lower scores indicating better OHRQoL (Locker and Allen 2002). In addition, The Orientation to Life (SOC-13) questionnaire was used to measure the sense of coherence (SOC) that may have modifying effects on the OHIP ratings. This questionnaire is a validated generic and multidimensional instrument that measures individual coping capacity (Antonovsky 1987; Antonovsky 1993). It has a seven-point Likert-scale format with two anchoring responses: "never or seldom" and "always or very often". The total range of the scale is 13–91 points. A higher score indicates a higher level of SOC.

2.2.1. Statistical analyses

The data were collected and transferred to SPSS version 17 statistical package (SPSS Inc, Chicago, IL, USA). General linear models repeated measures were used to assess the effect of time on the oral health-related quality of life (OHRQoL) (within-subjects factor) and differences between groups (between-subjects factor).

Bivariate statistical analyses were used to assess the association between the sense of coherence (SOC) and the Oral Health Impact Profile (OHIP-20) scores. SOC scores were analyzed in both continuous and categorical formats. Grouping was performed according to reported general population SOC scores (Kattainen *et al.* 2006; Statistics Canada 1995; Stephens *et al.* 1999). Subjects were categorized as strong (66–91),

moderate (39–65) or poor SOC (13–38). Paired *t*-tests were used to evaluate the stability of the SOC over time (first and second year follow-up).

Table 1: The RCT and follow up study inclusion and exclusion criteria
Source (Pan *et al.* 2008)

Inclusion criteria:	Exclusion criteria:
1. 65 years old and older 2. Completely edentulous for a minimum of 5 years 3. Wishing to replace existing conventional dentures 4. An adequate understanding of written and spoken English or French 5. Able to understand and respond to questionnaires used in the study 6. Wiling and able to accept the protocol and give informed consent 7. Wearing study prostheses 8. Participated in previous parts of the study	1. Insufficient bone to place two implants in the anterior mandible 2. Other oral conditions that preclude immediate prosthetic treatment 3. Acute or chronic symptoms of temporomandibular disorders. 4. History of radiation therapy to the orofacial region 5. Systematic or neurological disease that contraindicates implant surgery 6. Any neoplasia diagnosed less than 5 years previously 7. A BMI of less than 20 Kg/m2 or greater than 32 kg/m2 8. A score of 24 or less on the mini-mental state evaluation (to eliminate subjects with impaired cognitive functions) 9. Taking any of the following which will affect blood nutrient concentrations: dietary supplements, anti-neoplasic medication, phenytoin or corticosteroids. 10. Other conditions that jeopardize surgical treatment (e.g., Alcoholism) 11. Psychological or psychiatric conditions that could influence diet and reaction to treatment.

CHAPTER THREE: THE MANUSCRIPT AND

SENSE OF COHERENCE RESULTS

3.1. The Manuscript

Is oral health-related quality of life stable upon rehabilitation with mandibular two-implant overdentures?

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Abstract

Objectives: There is evidence of the need for clinical trials to investigate the long-term impact of mandibular two-implant retained overdentures (IODs) on the oral health-related quality of life (OHRQoL) of edentulous individuals. Furthermore, the stability of the effect remains unverified. The aim of this study was to determine the magnitude of the effect of IODs on the quality of life and assess the stability of this effect over time.

Methods: A cohort of participants (n = 172, mean age 71, SD = 4.5) wearing conventional dentures (CDs) or mandibular two-implant retained overdentures (IODs) were followed up for two years. Changes in ratings on the Oral Health Impact Profile (OHIP-20) were used as indicators of OHRQoL. General linear models were conducted to assess the effect of time, socio-demographic factors and their interaction with the type of prosthesis on the total and domains OHIP scores using three time points over the course of follow-ups.

Results: Statistically significant improvement in the OHRQoL was seen for both groups. This improvement was maintained over the two years of the assessment regardless of the type of prosthesis (Wilks's Lambda = 0.473, F (1,151) = 157.31, p < 0.0001). At both follow-ups, participants wearing IODs reported significantly better total OHIP scores compared to those wearing CDs. The magnitude of the effect was 1.5 times higher for IODs compared to CDs. A significant interaction effect was found between the pre-treatment OHIP score and type of prosthesis (Wilks's Lambda = 0.834, F (1,151) = 31.00, p < 0.0001). In the CD, individuals with low total OHIP scores at baseline had

significantly better OHRQoL scores at follow-up; those with high total OHIP scores at baseline had significantly worse OHRQoL scores at follow-up. This effect was not seen in the implant overdenture group.

Conclusions: The study extends the findings of prior research to confirm that mandibular two-implant retained overdentures provide better oral health-related quality of life than conventional dentures in the long-term. These results have both research and clinical relevance and provide additional information that enables clinicians to decide on treatments best suited for edentulous individuals.

Introduction

Public healthcare policies and strategies are based on hard evidence of the beneficial effect of interventions on the social and biological consequences of diseases. The quality, effectiveness and efficacy of interventions are often assessed by their impact on individuals' quality of life. In this regard, several studies (Allen *et al.* 2006; Awad *et al.* 2003b; Heydecke *et al.* 2005b; John *et al.* 2004) have been carried out to evaluate the efficacy and effectiveness of mandibular two-implant retained overdentures (IODs), which have been proposed as the minimum standard of care for edentulous individuals (Feine *et al.* 2002b; Thomason *et al.* 2009). However, there is still controversy regarding the superiority of this treatment over conventional complete dentures (CDs) in terms of oral health-related quality of life (OHRQoL) and the magnitude of the effect remains uncertain (Emami *et al.* 2009b). Furthermore, it is still unclear whether the treatment effect, which is the treatment outcome given the most favorable conditions (Anderson 1998), is stable over time. Individuals whose quality of life has changed can report different levels of quality of life when measures are repeated simply because expectations are based on experiences (Allison *et al.* 1997). Thus, longitudinal studies are needed to better assess the long-term outcomes of randomized controlled clinical trials. This assessment is essential to avoid the mis- and overestimation of the treatment effects in chronic conditions such as edentulism (Samson *et al.* 2008). Therefore, in this longitudinal study, a cohort of edentulous elders treated with either IODs or CDs was followed to determine whether participants' OHRQoL is stable over time. The influence of socio-demographic factors was also investigated. We tested the hypothesis that there is

a difference between individuals wearing CDs and IODs regarding the stability of their OHRQoL over the two-year study period.

Materials and methods

This manuscript reports the results of the first and second year data analyses of the longitudinal cohort study emerged from an earlier randomized controlled trial (RCT). This RCT was designed to assess the impact of mandibular two-implant retained overdentures (IODs) on nutritional status, diet and general health of a sample of edentulous elders and its details have been described previously (Emami *et al.* 2009a; Emami *et al.* 2008; Pan *et al.* 2008; Perri *et al.* 2006). This longitudinal prospective cohort study aimed to evaluate the impact of IODs on a set of clinical and psychological factors as well as on patient-based outcomes over one, two, five, ten and fifteen years. The study protocol was approved by the Université de Montréal and McGill University Board Review. Participants of the randomized clinical study were invited to re-participate in this longitudinal study. Baseline data of the initial RCT were considered the baseline data (T0) for this study. Participants who agreed to enroll in the follow-up study underwent a series of independent assessments at one (T1) and two (T2) years after delivery of the new prostheses (Figure 1). This study is carried out at McGill University and Université de Montréal in Montreal, Canada. The results on oral health-related quality of life (OHRQoL) are presented here.

The OHRQoL was evaluated using the Oral Health Impact Profile (OHIP-20). The validity and reliability of this instrument have been tested and reported (Awad *et al.* 2003b; Slade and Spencer 1994a). This questionnaire consists of 20 items covering seven

domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The total OHIP score ranges between 20–120 points with a lower score indicating a better OHRQoL.

The self-administered McGill questionnaire was applied for acquiring information regarding socio-demographic aspects at baseline and each follow-up (Awad *et al.* 2000a).

Statistical analyses

Based on the literature (Allen *et al.* 2006), 66 participants are required to have 90% power to detect a difference of 10% between groups at the 5% level with the OHIP total score as the outcome variable. Thus, the number of participants at the first and second year of this study was sufficiently powered to assess the OHIP-20 ratings according to the treatment received.

Data were analyzed using descriptive, bivariate and multivariate statistical tests. Comparisons between completers and dropouts were carried out using the chi-square test for categorical data and independent *t*-tests for continuous data (Table 1). Univariate and repeated measures general linear models as well as Bonferroni tests were conducted to assess the effect of time, socio-demographic factors and their interaction effects with the type of prosthesis on the total and domains OHIP scores. Independent *t*-tests were performed to compare between-group differences on OHIP scores at both follow-ups.

Effect size (ES) was estimated by calculating the difference between T0 and T2 divided by the standard deviation (SD) at T0 (Allen *et al.* 2006). ESs of <0.5, 0.5 < ES < 0.8 and > 0.8 were considered small, moderate and large respectively (Cohen 1988; Kazis *et al.* 1989).

Both completer data analyses and intention to treat analyses (ITT) were carried out. "Last observation carried forward" was chosen for the imputation method (Munro 2005). The significant level was set at $p \leq 0.05$. Data analyses were performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA).

Results

A total of 172 participants (mean age at T1 = 71, SD = 4.5) accepted to take part in this longitudinal cohort study. One hundred fifty three individuals (mean age at T2 = 73, SD = 4.3) participated in the second year of the study with a dropout rate of 11%. Reasons for the dropouts were loss of contact and medical problems unrelated to study participation. Individuals who withdrew at the second year had significantly ($p < 0.0001$) higher total OHIP scores than completers. Dropout rate was significantly higher among unmarried, divorced, widows and living alone individuals than those who were married or living with others (Table 1).

There was no difference between the two treatment groups according to socio-demographic and OHIP scores at baseline outcome (Emami *et al.* 2009a; Emami *et al.* Submitted).

The results of the repeated measures general linear models showed significant decreases in total OHIP scores (Wilks's Lambda = 0.473, $F (1,151) = 157.31$, $p < 0.0001$) and all its subscales ($p < 0.01$) from baseline to first and second year follow-up (Tables 2 and 3). Within-group comparisons revealed no statistically significant differences between T1 and T2 ($p > 0.05$) (Table 2) except for psychological disability for IOD group where the difference was significant ($p = 0.02$ paired *t*-test) (Table 3). Married individuals had a

better oral health-related quality of life (OHRQoL) than unmarried individuals at T1 (mean difference 5.20, 95% CI = [0.12–10.29], $p = 0.04$).

At both follow-ups, participants wearing IODs reported significantly better total OHIP scores compared to those wearing CDs (T1, mean difference = 8.39, 95% CI = [4.30–12.48], $p = 0.005$; T2, mean difference = 9.81, 95% CI = [5.35–14.28], $p < 0.0001$). Furthermore, they scored lower than the CD group for all OHIP subscales except social disability (at T1 and T2) and psychological disability (at T1). The magnitude of the effect was higher for IODs than CDs for OHIP scores and all subscales (Table 3).

The results of the general linear model analyses demonstrated a significant interaction effect between pre-treatment OHIP scores and type of prosthesis (Wilks's Lambda = 0.834, $F(1,151) = 31.00$, $p < 0.0001$). In the IOD group, individuals had a better OHRQoL regardless of their baseline OHIP scores. In the CD group, individuals with low or high total OHIP baseline scores had significantly better or worse OHRQoL respectively at follow-ups ($p < 0.0001$). No interaction was detected for the other investigated variables. The results of intention to treat (ITT) data analyses and completer data analyses were similar.

Discussion

The oral health-related quality of life (OHRQoL) is a legitimate construct for evaluating treatment outcome. The magnitude of the treatment effect and its stability are important criteria in clinical decision-making. The results of this study demonstrated that the OHRQoL improved following delivery of conventional dentures (CDs) or two-implant retained overdentures (IODs) and that the treatment effect was stable over time.

However, the magnitude of the treatment effect was significantly larger for the IOD group.

A recent meta-analysis (Emami *et al.* 2009b) confirmed the need for randomized controlled trials (RCTs) to assess the real magnitude of the effect of IODs on the OHRQoL. We believe that the results of this study will provide additional data and might clear up any ambiguity on this topic.

Dental care professionals seldom use OHRQoL measurements in clinical practice and they are unfamiliar with the interpretation of OHIP scores. Therefore, the magnitude of change in OHRQoL should be demonstrated in a context that is meaningful for health professionals and patients. An attempt to ascertain the magnitude of change that corresponds to a minimal important difference (MID) would interpret the clinical relevance of treatment effects. The MID can be defined as "the smallest difference in scores in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" (Jaeschke *et al.* 1989).

John *et al*. (2009) suggested that a 6 point difference in OHIP score could be considered the MID. In this study, the mean difference between pre-treatment OHIP-20 scores and each follow-up was between 25–27 points in the IOD group and 16–17 points in the CD group. Furthermore, the mean OHIP difference between the two treatment groups at both follow-ups was between 8–9 points. This difference corresponds to a 1.5 times larger effect size (ES) for the IOD group (ES = 1.29) compared to the CD group (ES = 0.85) (Table 3). These findings are in agreement with previous studies on this topic (Allen *et al.* 2006; Awad *et al.* 2000a; Awad *et al.* 2003b; Pan *et al.* 2008; Raghoebar *et al.* 2000) and

support the McGill and the York Consensus Statement (Feine *et al.* 2002b; Thomason *et al.* 2009).

There is some evidence that pre-treatment patients' OHRQoL (Heydecke *et al.* 2003) and satisfaction (Awad *et al.* 2003a) are predictors of post-treatment outcomes. In this study, although both treatment groups had similar baseline OHIP scores, the association between the pre-treatment OHIP score and post-treatment outcomes was only significant for the CD group. This suggests that individuals wearing CDs with an initial low OHRQoL benefit substantially from the effect of wearing IODs.

The influence of socio-demographic variables on the oral health perception is not widely reported. In this study, socio-demographic variables did not influence any of the treatment outcomes except for marital status. The effect of marital status on the oral health perception is controversial. Although some authors have not reported such differences (Awad *et al.* 2000a; Awad *et al.* 2003a; Heydecke *et al.* 2003), others have shown that dissatisfaction with oral conditions was higher among those unmarried (Jokovic and Locker 1997; Locker *et al.* 1997). In this study, unmarried subjects withdraw significantly more than married subjects. The variation in the perception of the treatment between married and unmarried subjects might explain the high dropout rate among unmarried individuals (Table 1).

Maintaining minimum dropouts is a major challenge in longitudinal studies. In this study, withdrawn individuals had a significantly lower OHRQoL than completers. This indicates the importance of OHRQoL on individuals' motivation.

Since participants in this study were edentulous elders with sufficient amount of bone to place two implants in the mandible, we should caution against generalizing the results of

this study to edentulous individuals with highly atrophic mandibles or those who require additional reconstructive surgery to place dental implants. Edentulous individuals with atrophic conditions should be included in the future clinical trials to evaluate the beneficial effect of implant overdentures in this population.

Conclusion

Mandibular two-implant retained overdentures maintain a better oral health-related quality of life than conventional dentures in the long-term. The large magnitude of the effect of this treatment supports its clinical relevance.

Acknowledgements

Randomized controlled trial of edentulous females and males aged ≥ 65 years, (T0), n = 255

127 Implant Overdentures IODs | Randomisation | 128 Conventional Dentures CDs

Withdrawn n=11: lack of interest, fear, illness

Withdrawn n=5: lack of interest, illness

116 received IODs

123 received CDs

Longitudinal cohort study
174 accepted and signed informed consent.
2 excluded: changing attachment system and not wearing study prostheses.

Withdrawn at 6 months, n= 3: lack of interest, illness, lost of contact.

Withdrawn at 6 months, n= 6: lack of interest, illness, lost of contact.

First year follow-up (T1), n= 172

IOD n=95 (F=51, M=44)

CD n=77 (F=41, M=36)

Withdrawn at 12 months, n=3: lack of interest, illness, lost of contact, deceased, moved.

Withdrawn at 12 months, n=8: lack of interest, illness, lost of contact, moved.

Withdrawn, n=10: diseased, illness, lost of

Withdrawn, n=9: illness, diseased, lost of

IOD n=110 (F=59, M=51)

CD n=109 (F=60, M=49)

Second year follow- up (T2), n= 153

IOD n=85 (F=46, M=39)

CD n=68 (F=33, M=35)

Figure 1: Study design and flow chart

Table 1: Demographic variables and OHIP scores according to dropouts and completers at two-year follow-up.

	Completers n = 153	Dropouts n = 19	*p* value
Age (SD)	70.4 (4.3)	72.2 (5.1)	0.10
Treatment group			
CD	68	9	0.80
IOD	85	10	
Gender			
Males	74	6	0.16
Females	79	13	
Marital Status			
Married	86	4	0.00
Single/separated/ divorced/widow	65	15	
No answer	2	2	
Living with			
Alone	55	13	0.00
With family/others	98	6	
Education			
Below college	95	9	0.30
College or higher	57	9	
No answer	1	1	
Employment			
Full/part time	10	0	0.25
Home/student/ unemployed/retired	143	19	
Income			
Less than 40,000	98	4	0.77
40,000 or more	39	12	
No answer	16	3	
Total OHIP (SD)	32.9 (13.3)	49.6 (30.4)	0.00

Table 2: Within-treatment group mean difference and 95% Confidence Interval (CI) between the baseline (T0) and each follow-up (T1, T2).

	T0-T1			T0-T2			T1-T2		
	Mean difference	95% CI	p	Mean difference	95% CI	p	Mean difference	95% CI	p
IOD	25.74	[20.68- 30.79]	< 0.0001	27.02	[21.92- 32.11]	< 0.0001	1.27	[-0.76-3.32]	0.217
CD	16.65	[12.72- 20.58]	< 0.0001	16.51	[12.41- 20.89]	< 0.0001	-0.13	[-2.50-2.23]	0.907
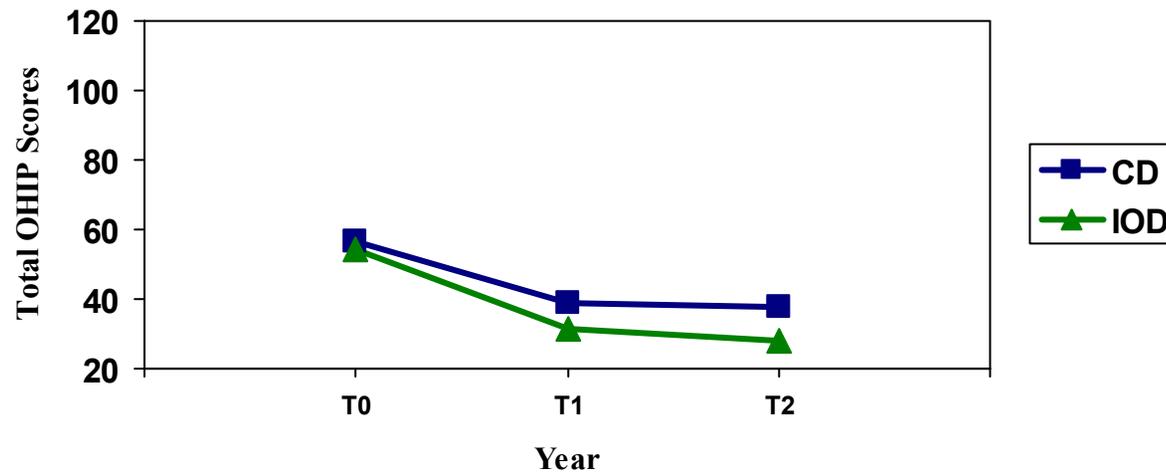
Figure 2: Completers' total OHIP -20 scores at baseline (T0), first (T1) and second (T2) year of the study

Table 3: Completers' total and domains OHIP-20 scores at baseline (T0), first year (T1) and second year (T2) of the study.

	CD n=68				IOD n=85			
	Baseline (T0)	First year (T1)	Second year (T2)	ES* T0-T2	Baseline (T0)	First year (T1)	Second year (T2)	ES* T0-T2
	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)	
Functional Limitation	11.6 (3.6) [a]	7.8 (3.6) [a, b]	7.5 (3.7) [a, b]	1.1	11.5 (3.7) [a]	6.4 (2.7) [a, b]	5.9 (3.0) [a, b]	1.5
Physical Pain	12.7 (4.9) [a]	9.2 (4.4) [a, b]	9.0 (4.4) [a, b]	0.7	12.8 (5.0) [a]	6.3 (2.6) [a, b]	6.3 (3.0) [a, b]	1.3
Psychological Discomfort	5.8 (3.0) [a]	3.7 (2.1) [a, b]	3.8 (2.4) [a, b]	0.6	6.0 (2.7) [a]	2.8 (1.7) [a, b]	2.7 (1.4) [a, b]	1.2
Physical Disability	10.8 (5.0) [a]	7.0 (3.3) [a, b]	7.3 (3.7) [a, b]	0.7	10.4 (5.1) [a]	5.0 (1.8) [a, b]	4.8 (1.9) [a, b]	1.0
Psychological Disability	5.2 (2.5) [a]	3.7 (1.9) [a]	3.8 (2.1) [a, b]	0.5	5.5 (2.5) [a]	3.1 (1.7) [a, c]	2.7 (1.2) [a, b, c]	1.1
Social Disability	4.2 (2.4) [a]	3.3 (1.6) [a]	3.4 (1.9) [a]	0.3	4.5 (2.9) [a]	3.1 (0.6) [a]	3.1 (0.5) [a]	0.4
Handicap	3.6 (2.1) [a]	2.6 (1.4) [a, b]	2.6 (1.7) [a, b]	0.4	4.0 (2.3) [a]	2.2 (0.6) [a, b]	2.0 (0.5) [a, b]	0.8
Total OHIP Scores	54.2 (19.2) [a]	37.5 (15.6) [a, b]	37.7 (17.6) [a, b]	0.8	54.9 (20.9) [a]	29.1 (9.8) [a, b]	27.8 (9.8) [a, b]	1.2

[*] ES: Effect size
[a] Significant within-treatment group difference between baseline, T1 and T2 ($p < 0.05$).
[b] Significant between-treatment group difference between T1 and T2 ($p < 0.05$).
[c] Significant within-treatment group difference between T1 and T2 ($p < 0.05$).

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3.2. Sense of coherence results

A total of 172 participants (mean SOC = 70, SD = 9.5, range: 38–91) filled out The Orientation to Life (SOC-13) questionnaire at the first year and 153 participants (mean SOC = 71, SD = 9.9, range: 42–88) filled out the questionnaire at the second year follow-up. No significant difference was found between dropout and completers ($p = 0.153$ independent t-test). Unmarried individuals and those who lived alone rated their total SOC lower than married individuals and those living with others (Table 1). No statistically significant difference was observed on the total SOC scores between T1 and T2 ($p = 0.21$ paired t-test).

The correlations between OHIP scores and SOC scores were low and negative (the r values ranged from –0.148 to –0.206, $p < 0.01$). According to categorization based on tertile values, most participants showed a strong SOC score (66–91) and only one participant at T1 was in the poor SOC group (13–38) (Table 2). SOC did not influence total OHIP scores at T1 or T2 ($F_{(1.167)} = 0.99$, $p = 0.37$ and $F_{(1.149)} = 1.54$, $p = 0.21$ respectively). In addition, the interaction effect between the SOC and the treatment group was not significant at both follow-ups ($F_{(1.167)} = 0.00$, $p = 0.95$ at T1 and $F_{(1.149)} = 0.08$, $p = 0.77$ at T2). The results of completers' data analyses and the intention to treat (ITT) analyses were similar.

Table 1: SOC scores at T1 according to the treatment group and socio-demographic variables.

	Total SOC (SD) at T1, n=172	*p* value
Treatment group		
CD	70.76 (9.9)	0.91
IOD	71.54 (10.0)	
Gender		
Males	71.14 (9.3)	0.228
Females	70.10 (9.3)	
Marital Status		
Single/separated/ divorced/widow	68.53 (9.8)	0.03
Married	71.66 (9.2)	
Living with		
Alone	68.19 (9.8)	0.02
With family/others	71.57 (9.2)	
Education		
Below college	69.70 (0.0)	0.30
College or higher	71.27 (8.8)	
Employment		
Full/part time	71.20 (9.6)	0.74
Home/student/ unemployed/retired	70.17 (9.6)	
Income		
Less than 40,000	69.20 (9.7)	0.13
40,000 or more	71.72 (7.9)	

Table 2: Total OHIP scores according to SOC (tertile values) and type of prosthesis.

Type of the prosthesis	SOC level	Year 1			Year 2		
		Mean OHIP scores	(SD)	n (%)	Mean OHIP scores	(SD)	n (%)
IOD	Poor	34.00	-	1 (1.1)	-	-	-
	Moderate	34.31	(20.0)	26 (28.4)	31.05	(15.1)	19 (22.3)
	Strong	30.20	(11.9)	68 (71.5)	26.98	(7.6)	66 (77.6)
	Total	31.36	(14.5)	95 (100)	27.89	(9.8)	85 (100)
CD	Poor	-	-	-	-	-	-
	Moderate	41.63	(19.3)	22 (28.5)	39.61	(23.5)	17 (25)
	Strong	37.85	(18.3)	55 (71.4)	37.07	(15.4)	51 (75)
	Total	38.93	(18.5)	77 (100)	37.71	(17.6)	68 (100)
Total	Poor	34.00	-	1 (0.5)	-	-	-
	Moderate	37.67	(19.8)	48 (27.9)	35.09	(19.7)	36 (23.5)
	Strong	33.62	(15.5)	123 (71.5)	31.38	(12.6)	117 (76.4)
	Total	34.75	(16.8)	172 (100)	32.25	(14.6)	153 (100)

CHAPTER FOUR: DISCUSSION

4. Discussion

4.1. The oral health-related quality of life

In this study, the oral health-related quality of life (OHRQoL) improved significantly from baseline to the first and second year follow-ups in both treatment groups. The improvement in the mandibular two-implant retained overdenture (IOD) group was significantly higher than that in the conventional denture (CD) group. Similar results were reported by Awad *et al.* (Awad *et al.* 2000a; Awad *et al.* 2003a; Awad *et al.* 2003b) who conducted two randomized controlled trials (RCTs) to assess the change in the OHRQoL after delivery of new CDs or IODs using the OHIP-20 and OHIP-49 scales. The results of both RCTs demonstrated significant decreases in the post-treatment OHIP ratings compared to the pre-treatment ratings for both treatment groups with significantly better OHRQoL in the IOD group compared to the CD group. However, Allen *et al.* (2006) used an intention to treat (ITT) analysis and reported significant improvement in the OHRQoL with IOD and CD prostheses with no differences between the two treatment groups. The absence of significant differences between the two study groups in Allen *et al.* (2006) might be attributed to participants' views and expectations of IODs and the unclear high dropout rate among participants who were randomized to receive their treatment of choice (Awad 2007). Therefore, it seems that participants wearing IODs experience significantly better OHRQoL than those wearing CDs.

In the current study, both treatment groups showed no statistically significant changes in the oral health-related quality of life (OHRQoL) between the two follow-ups, indicating

stability in the outcome perception. The magnitude of improvement was 1.5 times higher in the IOD group than in the CD group. Heydecke *et al.* (2003) used the same sample population as Awad *et al.* (2003b) and reported a 2.5 times higher magnitude of improvement in the IOD group compared to the CD group. The higher ratio in Heydecke *et al.* (2003) is mainly because of the difference in CD ratings (ES = 0.4 vs. ES = 0.8). Since the ES for IODs was similar in both studies, this explains the difference in the ratio of magnitude of improvement. From these two studies it seems that the magnitude of improvement in the CD groups is smaller and more variable than in the IOD groups.

The results of the present study showed statistically significant within- and between- group differences in the oral health-related quality of life (OHRQoL). The mean difference between the pre-/post-treatment OHIP-20 scores was 25–27 points in the IOD group and 16–17 points in the CD group with 8–9 points the between-group difference (Table 2, The manuscript). John *et al*. (2009) suggested that a 6 point difference on the total OHIP scale could be considered the minimally important difference (MID) when determining the smallest clinically meaningful change. As a result, both groups in the current study experienced clinically meaningful improvements compared to baseline, with those who received IODs experiencing more clinical benefit than those who received CDs.

The quality of life concept was used in the current study as an outcome measure to capture not only the physical aspect of health but also the extent of well-being on patients' health. Previous studies have used patient-based measures, such as patients' satisfaction, stability of prostheses and chewing ability, to assess the outcomes of both treatments. However, those instruments might not reflect the impact of treatment on patients' quality of life.

The Oral Health Impact Profile (OHIP-20) questionnaire, which is a patient-based disease-specific questionnaire, was used in the current study to evaluate the oral outcomes. The OHIP-20 is still the most widely validated disease-specific instrument used to evaluate the quality of life of edentulous elders wearing complete prostheses. Although other versions of the OHIP could have been used, the OHIP-49 is too long for usual clinical settings and the OHIP-14 does not contains questions about the wear of prosthesis (Allen and Locker 2002). Generic measurements can also be used in addition to disease-specific measurements when assessing the treatment outcomes (Allen 2003). However, those instruments lack sensitivity and responsiveness to oral conditions and might not be able to detect clinically meaningful changes (Allen *et al.* 1999; Fletcher *et al.* 1992; Heydecke *et al.* 2003).

Consequently, the results of the present study show the clinical superiority of mandibular two-implant overdentures (IODs) over conventional dentures (CDs) in terms of oral health-related quality of life (OHRQoL). The magnitude of improvement in the IOD group was higher than the CD group and was stable over time. This supports the McGill Consensus Statement (Feine *et al.* 2002b) and the York Consensus Statement (Thomason *et al.* 2009), which establish IODs as the treatment of choice for patients suffering from complete tooth loss. Therefore, these results are clinically significant and provide clinicians with guidelines supporting the vision that IODs should be considered the contemporary standard of care in clinical planning for edentulous people.

4.2. The Sense of coherence

The outcomes of the present study confirm the results that the sense of coherence (SOC) is stable in the elderly population. No difference was detected in the ratings of the SOC between the first and second year follow-up. This is in agreement with previous publications showing that the SOC is stable overtime (Kuuppelomaki and Utriainen 2003; Nilsson *et al.* 2003; Suominen *et al.* 2001). However, Smith *et al.* (2003) demonstrated that environmental factors, such as socio-economic variables and work conditions, can affect the SOC over time. Furthermore, Snekkevik *et al.* (2003) reported a change in the level of SOC after severe physical trauma. In our study, data regarding positive and negative life events were not gathered. Therefore, the association between life events and individuals who experienced change in their SOC levels could not be tested.

The results of the current study indicate that the sense of coherence (SOC) is not clinically associated with the perception of the oral health-related quality of life (OHRQoL). The correlation coefficients (the *r* values) were low and the SOC did not influence the OHRQoL. However, other studies demonstrated an association between the perception of SOC and oral health behaviours. Bonanato *et al.* (2009) reported that mothers with low SOC were more likely to have children with decayed and filled teeth. Savolainen *et al.* (2005a) concluded from a national survey that dentate adults with "strong" or "moderate" SOC have significantly better OHRQoL than those with "poor" SOC. The insignificant association in our study between the SOC and OHRQoL might be attributed to our homogeneous population where the majority of participants had a "strong" SOC level and

only a few had "moderate" or "poor" SOC levels. In other words, there were too few variations in the SOC to detect a significant association with the OHRQoL.

Most participants recruited for the present study had a strong sense of coherence (SOC) level. The mean SOC scores (71, SD = 9.9, range: 42–88) in our population was higher than the average Canadian scores (range 43–47) for the same age group reported in the National Population Health Survey (NPHS) (Statistics Canada 1995; Stephens *et al.* 1999). In the present study, the sample population was composed of elders wishing to replace their prostheses and improve their oral health. Eriksson and Lindstrom (2005) indicated in their systematic review that older adults have higher SOC than younger adults. Savolainen *et al.* (2005b) suggested that maintaining good oral health can be considered a challenge that requires psychological resources, such as strong SOC. This probably explains why most participants had "strong" SOC and few participants had "moderate" or "poor" SOC levels. Consequently, the results of the present study might be limited to people with high SOC level and might not be able to be generalized to those with low SOC level.

Married participants and those living with others rated, in the current study, their sense of coherence (SOC) higher than unmarried individuals and those living alone did. While this particular finding is rarely discussed in the literature, the association between social support and the SOC has previously been mentioned (Eriksson and Lindstrom 2007; Volanen *et al.* 2007). Middle-aged widows reported higher severity of life events and lower social support than married women (Ungar and Florian 2004). Although the lack of social support is difficult to quantify and is out of the scope of the present study, it seems reasonable to think

that unmarried individuals and those living alone might have less social support than their married and living with others counterparts.

4.3. Issues of longitudinal studies

In the present study, the rate of dropout was 11% over a one-year period. Reasons for dropouts included loss of interest, loss of contact and medical problems. A trained coordinator helped to contact the participants and organize the follow-up sessions. Each participant received a reminder call on the day before their appointment. Participants who did not attend their appointments were given other appointments according to their preferences. In addition, location flexibility was offered for those who favored the dental clinic at the Montreal General Hospital rather than the dental clinic at the Université de Montréal. Shumaker *et al.* (2000) described three prevention strategies to enhance adherence in longitudinal studies. Primary strategies include the careful choosing and enrolling of study participants. Secondary strategies composed of the early identification of signs of slippage. Tertiary methods referred to tracking participants who become poorly adhered. Although the use of such strategies and multicenter locations seems effective in decreasing dropouts, these procedures require a considerable amount of time, resources and energy.

The dropout rate in the current study did not influence the population homogeneity because participants dropped out almost equally in the two treatment groups. A high dropout rate harms the randomization by introducing potential biases because of the change in the

population characteristics. In addition, the loss of participants in one group over the other leads to a loss of study homogeneity (Janson *et al.* 2001). This challenge became extremely difficult because of the elderly population in the current study. These participants feel the burden of travelling to attend follow-up sessions, particularly if they live alone in nursing homes or in distant geographic areas. Therefore, allowing participants to attend follow-up sessions in dental centers in their community may help minimize dropouts.

4.4. Study limitations

This study is limited by its population and this has made the external validity less than desired. Participants came from a previous randomized controlled trial evaluating the nutritional health and were selected according to rigorous inclusion criteria (Table 1, Chapter 2). This might affect the generalization of results to medically compromised populations whose perception of health might overshadow their perception of quality of life. In addition, the results of this study might not be representative to those with severe mandibular atrophy and patients who require surgical reconstruction to place dental implants.

In addition, potential bias might have resulted from the use of patients' centered measures. Participants' ratings of the oral health-related quality of life (OHRQoL) could be influenced by their treatment preference or other cultural, psychological or interpersonal factors such as the clinical setting and relationship with the clinicians (Awad *et al.* 2000b; Feine *et al.* 1998; Guillemin *et al.* 1993; Mangalik and Neidhart 1992).

Finally, this study did not test the influence of the number of implants and the prostheses design on treatment outcomes. Consequently, the results should be interpreted with caution when considering other implant overdenture prostheses because the outcome might be associated with the amount of aftercare and maintenance required for each design (Meijer *et al.* 2009; Stoker *et al.* 2007).

4.5. Future studies

Future trials should investigate the beneficial effect of implant therapy in more specific populations such as medically compromised participants or those with severe mandibular atrophy. In addition, potential bias should be avoided by the administration of preference clinical trials. Finally, different types of prostheses should be tested to determine the number of implants and the design that provides the maximum benefit at optimal cost.

CHAPTER FIVE: CONCLUSIONS

5. Conclusion

Within the limitations of the current study, we conclude that:

1- There is a difference in the treatment effect on oral health-related quality of life in favor of edentulous individuals who wear mandibular two-implant retained overdentures with individual ball attachments compared to those who wear conventional dentures.

2- The treatment effect of these two interventions on the oral health-related quality of life is stable time.

3- The sense of coherence is stable over time and it does not influence the treatment outcome.

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ANNEXES

Annex I: The McGill self-administrated socio-demographic questionnaire

Socio-demographic Questionnaire

Identification Code: Date

☐☐☐☐☐☐☐☐   ☐☐☐ / ☐☐ / ☐☐

                                          y y   m m   d d

Please answer the following questions.

Gender	O Male	O Female	
Native Language	O French	O English	O German
	O Spanish	O Other	
Marital status	O Single	O Married	O Separated
	O Divorced	O Widow	
Do you live	O Alone?		O With family?
	O With other adults?		
	O I prefer not to answer		
Level of education	O Elementary (7 years and less)		O High-school (8-12 years)
	O College (13-15 years)		O University (16 years and more)
	O prefer not to answer		
Present employment	O Full time		O I prefer not to answer
	O At home		O I prefer not to answer
	O Unemployed		O Retired
	O I prefer not to answer		
Annual household revenue	O Less than 19 999$		O Between 20 000 and 29 999$
	O Between 30000 and 39 999$		O Between 40 000 and 49 999$
	O Between 50 000 and 59 999$		O Between 60 000 and 74 999$
	O more than 75 000$		
	O prefer not to answer		

Annex II: The Orientation to Life (SOC -13) questionnaire

SOC -13 Questionnaire

Identification Code: Date

				/			/		
		y	y		m	m		d	d

Here is a series of questions relating to various aspects of our lives. Each question has seven possible answers. Please mark the number which expresses your answer, with numbers 1 and 7 being the extreme answers. If the words under 1 are right for you, circle 1; if the words under 7 are right for you, circle 7. If you feel differently, circle the number which best expresses your feeling. Please give only one answer to each question.

1. Do you have the feeling that you don't really care about what goes on around you?

1	2	3	4	5	6	7
very seldom or never						very often

2. Has it happened in the past that you were surprised by the behavior of people whom you thought you knew well?

1	2	3	4	5	6	7
never happened						always happened

3. Has it happened that people whom you counted on disappointed you?

1	2	3	4	5	6	7
never happened						always happened

4. Until now your life has had:

1	2	3	4	5	6	7
no clear goals or purpose at all						very clear goals and purpose

5. Do you have the feeling that you're being treated unfairly?

1	2	3	4	5	6	7
very often						very seldom or never

6. Do you have the feeling that you are in an unfamiliar situation and don't know what to do?

1	2	3	4	5	6	7
very often						very seldom or never

7. Doing the things you do every day is:

1	2	3	4	5	6	7
a source of deep pleasure and satisfaction						a source of pain and boredom

8. Do you have very mixed

1	2	3	4	5	6	7
very often						very seldom or never

9. Does it happen that you have feelings inside you would rather not feel?

1	2	3	4	5	6	7
very often						very seldom or never

10. Many people - even those with a strong character - sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?

1	2	3	4	5	6	7
never						very often

11. When something happened

1	2	3	4	5	6	7
you overestimated or underestimated its importance						you saw things in the right proportion

12. How often do you have the feeling that there's little meaning in the things you do in daily life?

1	2	3	4	5	6	7
very often						very seldom or never

13. How often do you have feelings that you're not sure you can keep under control?

1	2	3	4	5	6	7
very often						very seldom or never

Annex III: The Oral Health Impact Profile (OHIP -20) questionnaire

OHIP -20 Questionnaire

Identification Code: Date

| | | | | | | | | |

| | | | / | | | / | | |
y   y   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	O	O	O	O	O
2	Have you had food catching in your teeth or dentures?	O	O	O	O	O	O
3	Have you felt that your dentures have not been fitting properly?	O	O	O	O	O	O
4	Have you had painful aching in your mouth?	O	O	O	O	O	O
5	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
6	Have you had sore spots in your mouth?	O	O	O	O	O	O
7	Have you had uncomfortable dentures?	O	O	O	O	O	O
8	Have you been worried by dental problems?	O	O	O	O	O	O
9	Have you been self conscious because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
10	Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
11	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
12	Have you been unable to eat with your dentures because of problems with them?	O	O	O	O	O	O
13	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O

	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?	O	O	O	O	O	O
15	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
16	Have you avoided going out because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
17	Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
18	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O
19	Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or	O	O	O	O	O	O
20	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	O	O	O	O	O	O