Dietary intake differences between patients wearing two-implant mandibular overdentures and conventional dentures: A randomized controlled parallel trial

By

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ABSTRACT

Objectives: It has been shown that people wearing mandibular two-implant overdentures (IOD) have less difficulty chewing harder/tougher food than those wearing conventional complete dentures (CD). However, there is still controversy over whether or not ease of chewing results in better dietary intake. In this randomized clinical trial, the amounts of total dietary fiber (TDF), macronutrients, nine micronutrients and energy in diets consumed by IOD and CD patients were compared using information gained from three 24-h food recalls. We aimed to determine whether providing simple implant retained dentures to elderly edentulous individuals gives them a significantly better nutritional profile than those who receive conventional dentures

Methods: Two hundred fifty-five male and female edentate patients (> 65 yrs) were randomly divided into two equal groups and assigned to receive a maxillary CD and either an IOD or a CD for the mandible. Two hundred seventeen participants (CD = 114, IOD = 103) completed the one-year protocol, then reported the food types and quantities they consumed to a registered dietician through a standard 24-hour recall method. The data collected were analyzed using nutrient values from the Canadian Nutrient File with the help of specialized software from the McGill University Faculty of Dietetics and Human Nutrition.

The mean values of TDF, macro- and micronutrients and energy consumed by both groups were calculated and compared analytically.

Results: No significant between-group differences were found, even with sex stratification (*p*s>0.17). No between-group difference was found in intake of TDF (*p*s> 0.36), energy (*p*s> 0.58) or macronutrients, i.e. proteins, fats or carbohydrates (*p*s> 0.41) at baseline and one year post-treatment. There were also no significant differences between the two groups for any of the nine examined micronutrients (Vitamin A, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Thiamin, Riboflavin, Folate, and Niacin; *p*s> 0.13). A non-significant correlation was observed for the association between all dependent variables (TDF, energy, macro- and micronutrients) and treatment after adjustment for baseline values and sex.

Conclusions: Although there is considerable evidence supporting the adoption of two-implant mandibular overdenture (IOD) treatment as the standard of care for edentate patients, this study does not indicate an improvement in dietary intake at one year for healthy independent edentate elders who are not given specific dietary counseling. (International CT Registration#: ISRCTN24273915).

Keywords: Randomized Clinical Trial, Nutrition/ Nutritional Sciences, Dental Implant(s), Edentulous/ edentulism, Geriatric Dentistry, Prostheses, Removable prosthodontics.

RÉSUMÉ

Objectifs: Il a été démontré que les patients portant des prothèses mandibulaires supportées par deux implants (PI) mastiquent la nourriture avec moins de difficulté que ceux portant des prothèses dentaires complètes conventionnelles (PC). Cependant, il existe toujours une controverse concernant si cela se traduit ou non en un meilleur apport alimentaire. Dans cet essai clinique randomisé, les quantités de fibres alimentaires totales (FAT), de macronutriments, de neuf micronutriments et d'énergie dans l'alimentation de patients PI et PC ont été comparées en utilisant de l'information provenant de trois rappels d'aliments consommés sur 24h. Nous visions à déterminer si le fait de fournir une prothèse dentaire simple retenue par des implants à des individus édentés âgés leur donne un profil nutritionnel significativement meilleur que ceux qui reçoivent des prothèses conventionnelles.

Méthodes: Deux cent cinquante-cinq patients édentés masculins et féminins (> 65 ans) ont été répartis au hasard en deux groupes égaux et assignés à recevoir une PC maxillaire et soit une PI ou une PC pour la mandibule. Deux cent dix-sept participants (PC = 114, PI = 103) ont complété le protocole d'un an, puis ont rapporté les types d'aliments et les quantités consommées à un diététiste professionnel par une méthode standard de rappel sur 24h. Les données recueillies ont été analysées en utilisant les valeurs nutritives tirées du Fichier

canadien sur les éléments nutritifs à l'aide d'un logiciel spécialisé de la Faculté de diététique et de nutrition humaine de l'Université McGill. Les valeurs moyennes de FAT, de macro- et micronutriments et d'énergie consommées par les deux groupes ont été calculées et comparées analytiquement.

Résultats: Aucune différence significative intergroupe n'a été trouvée même avec une stratification selon le sexe (*p*s> 0.17). Aucune différence significative intergroupe n'a été trouvée dans l'apport de FAT (*p*s> 0.36), d'énergie (*p*s> 0.58) ou de macronutriments, i.e. protéines, gras ou glucides (*p*s> 0.41), au début de l'étude et un an post-traitement. Il n'y avait également aucune différence significative entre les deux groupes pour aucun des neuf micronutriments examinés (vitamine A, vitamine B6, vitamine B12, vitamine C, vitamine D, thiamine, riboflavine, folates et niacine) (*p*s> 0.13). Une corrélation non significative a été observée pour l'association entre toutes les variables dépendantes (FAT, énergie, macro- et micronutriments) et le traitement après ajustement pour les valeurs initiales et le sexe.

Conclusions: Bien qu'il existe de nombreuses données soutenant l'adoption d'un traitement avec des prothèses mandibulaires supportées par deux implants (PI) comme norme de soins pour les patients édentés, ces preuves n'incluent pas une amélioration dans l'apport alimentaire après un an pour des personnes âgées édentées indépendantes et en bonne santé à qui l'on ne fournit pas de conseils diététiques spécifiques. (# Enregistrement international d'ECR : ISRCTN24273915).

Mots- clés : Essai clinique randomisé, nutrition/ sciences de la nutrition, implant(s) dentaire(s), édenté/ édentation, médecine dentaire gériatrique, prothèses, prothèses amovibles.

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CONTRIBUTION OF CANDIDATE & MANUSCRIPT CO-AUTHORSHIP

1- The candidate carried out the statistical analysis and interpretation of the dietary intake data for the first year of the study, which is the subject of this candidate's Masters degree project.

2- In addition to sharing findings with other colleagues and professors at the Faculty of Dentistry, McGill University, the candidate presented the findings of this research project at the following major events:

- The ***91st General Session & Exhibition of the International Association for Dental Research (IADR)***, held in conjunction with the ***42nd Annual Meeting of the American Association for Dental Research (AADR)*** and the ***37th Annual Meeting of the Canadian Association for Dental Research (CADR)***, at the Washington State Convention Center, Seattle, Washington, USA

  March 2013 - Oral Presentation

- The ***Annual Scientific Day of the Network for Oral and Bone Health Research (RSBO)***, Université de Montréal, Montreal, Canada

  November 2012. - Oral Presentation

- The ***2013 Canadian Dental Research Student Workshop: Careers in Academic Dentistry***, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada.

  June 2013 Poster Presentation.

- The ***8th Annual Research Day of the Faculty of Dentistry***, McGill University, Montreal, Canada

  March 2013 - Oral Presentation

- The ***Annual Students' Table Clinics Day***, Faculty of Dentistry, McGill University, Montreal, Canada.

  February 2013 - Poster Presentation

3- In addition to the previous roles (reviewing the literature, analyzing and interpreting dietary intake data for the first year of the study), the candidate wrote all sections of the manuscript (Do Implant Overdentures Improve Dietary Intake?: A Randomized Clinical Trial). However, the following co-authors were also involved as follows:

- K. Gray-Donald - Protocol development for the dietary assessment, analysis of the diet data, as well as interpretation of dietary and nutritional data.
- M. Awad - Protocol development and quantile regression analysis of the dietary data.
- L. Johnson-Down - Analysis of diet data using specialized dietary software.

- S. Wollin - Protocol development and data gathering.
- J.S. Feine, (Study PI) - Development of the protocol, co-ordination of the study, analysis and interpretation of the data and final editing of the research manuscript.

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ABBREVIATIONS AND ACRONYMS

BSSPD	British Society for the Study of Prosthetic Dentistry
CD	Conventional Complete Denture
CDs	Conventional Complete Dentures
CI	Confidence Interval
CIHR	Canadian Institutes of Health Research
CRP	C-reactive Protein
HEI	Healthy Eating Index
IOD	Implant overdenture
IODs	Implant overdentures
IRB	Institutional Review Board
LEMONADE	Longitudinal Evaluation of Multi-phasic, Odontological and Nutritional Associations in Dentists
Mand.	Mandibular
Max.	Maxillary
MNA	Mini Nutritional Assessment
NDNS	the British National Diet and Nutrition Survey
NHANES III	3rd US National Health and Nutrition Examination Survey
NOHS	Nutrition and Oral Health Study
OHIP	Oral Health Impact Profile
OHRQoL	Oral Health Related Quality of Life
QoL	Quality of life
RCT	Randomized controlled trial
SPSS	Statistical Package for the Social Sciences
STD	Standard Deviation
tHcy	Homocysteine
TDF	Total Dietary Fiber
VAS	Visual analog Scale

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DEDICATION

To my parents… I perfectly recall how hard raising a restless boy like me was! I can still remember your tears and fear-filled faces when I had to undergo surgery to fix my badly broken arm, when I jumped off the roof at the age of six thinking that I will fly like a superman, when I made the huge tree trunk fall over my little head to almost smash it, etc… Well, maybe I was not the perfect boy a father and mother would like to have, but at least, I hope that you currently have a different opinion. My love and gratitude to you goes beyond words. I miss you, love you and wish to meet you soon!

To my better half, Aziza… Thanks for believing in me and pushing me forward to follow a twelve-year-delayed dream. You are the only person who believed that my decision to leave our comfortable life in Qatar, immigrate to Canada and go back to school was not a stupid one. Since you got stuck with this crazy man ten years ago, you have always supported me on the expense of your own comfort and life plans. Being there besides me makes me determined to continue on going whenever things seem to be so hard or even impossible. Today I celebrate and share this humble scientific contribution with you. Thanks for everything you did for me and for our children. I love you!

To Omar and Adam, my two great little men… I am so sorry for keeping moving around. I know how hard it is for you to keep learning new languages, dealing with different cultures, making new temporary friendships, and being away of family… I can see and understand your suffering trying to cope with dad's tough, and what might look now to you senseless, decisions… I know how hard all this is. I am really sorry, but one day you will grow up and know that I did it all for you, I simply want you to have a better life than the one I had; maybe after I die you will read these lines and pray to God to forgive me and to make my soul rest in paradise. I am so proud of you and will continue to love you unconditionally!

CHAPTER 1

INTRODUCTION

1.1 Overview of Terms (Definitions)

Edentulism

e·den·tul·ism (ē-dentyū-lizm)
State of being partially or completely without teeth.

Medical Dictionary for the Dental Professions © Farlex 2012

Complete Denture (CD)

com·plete den·ture (kom'plēt den'chŭr)
Dental prosthesis that is a substitute for the lost natural dentition and associated structures of the maxillae or mandible.
Synonym: full denture.

Medical Dictionary for the Dental Professions © Farlex 2012

Figure 1. Conventional Removable Mandibular Complete Denture

Implant Denture/ Overdenture (IOD)

im·plant den·ture (im'plant den'chŭr)
A denture that receives its stability and retention from a substructure that is partially or wholly implanted under the soft tissues of the denture basal seat.

Medical Dictionary for the Health Professions and Nursing © Farlex 2012

Figure 2. Mandibular Two-implant Overdenture

1.2 Background and Significance

A large population in Canada and other countries, particularly the low-income elderly, are missing all of their teeth (edentulous). More than half of Canadians over 65 were edentulous in 1988, with the highest percentage in Quebec (72%) [1]. Twenty years later, this dropped to 58% [2,3]. Even though the situation has improved, according to a recent survey (*the Canadian Health Measures Survey 2007–2009*), 6% of all Canadians between 20 and 79 years of age are edentulous. The rate rises to 22% in the 60-79 age group [4]. Quebequers in the lowest socio-economic brackets are 6 times more likely to be edentulous than high-income earners [3]. Polzer et al. [2] reported the prevalence of edentulism in 42 selected countries, taken from peer-reviewed publications and the WHO website (www.who.int/en). According to this, the percentage of edentulism worldwide ranged from 1.3% to 78.0% for the 65+ age group. Amongst people aged 65 years and over in seven industrialised nations (Canada, France, Germany, Italy, Japan, the United Kingdom and the United States), Canada had the highest prevalence of edentulism (58%), while France had the lowest (16.3%). In developing countries, the prevalence of edentulism ranged from 1.3% in Nigeria to 78% in Bosnia-Herzegovina. Within the more developed nations, Switzerland has the lowest prevalence of edentulism (13.8%) among the adult population aged 65 to 74 years. Polzer et al. has concluded that, taking into account ageing of the global

population, there will be a relevant proportion of edentulous individuals in ageing societies worldwide. Clearly, the high demand for treatment of edentulism will continue for many decades in Canada [5,6] and, similarly, in the rest of the world.

Until recently, conventional complete dentures (CDs) were the only prosthetic devices available to edentulous people. They rest on the mucosa over the bony ridges of the mandible and the maxilla. When teeth are extracted, most edentulous patients rapidly lose alveolar bone and then suffer a progressive loss of the underlying basal bone [7-10]. With time, many patients are left with insufficient bone to support complete dentures, particularly the mandibular one, which is easily dislodged by movement of the tongue and cheeks [11]. Therefore, even when a patient is given new CDs, diet may not substantially improve [12-14]. With the advent of cylindrical intra-osseous implants [15], secure and stable retention of prostheses has become possible [12,16]. Many long-term studies of titanium root-form single and 2-stage implants demonstrate their safety, longevity and efficacy [12,17-22]. Moreover, being in direct contact with the jaw-bone, dental implants provide two important advantages. First, dental implants reduce or even prevent the vertical and horizontal loss of alveolar peri-implant bone. Several studies have shown that the amount of peri-implant bone loss is 7 to 10-fold reduced compared to similar sites without implants [10,23-26]. This reduced peri-implant bone atrophy suggests a prophylactic indication for dental

implants in order to prevent severe ridge resorption, denture instability, pain and recurrent sore spots, as well as potential exposure of the mental nerve and risk of mandibular fracture [2]. Second, dental implants improve the tactile sensitivity lost with the loss of natural teeth and associated periodontal tissues; this effect is called “osseoperception” [27]. Jacob and van Steenberghe proposed that this implant-mediated sensory-motor control may have important clinical implications, because a more natural functioning with implant-supported prostheses can be attempted [28]. Osseoperception might also explain some of the improved functional aspects of IODs. It implies that the feedback pathway to the sensory cortex, lost after the extraction of teeth, could be partly restored with placement of an implant [29]. Such physiological integration may assist natural functioning with implant-borne prostheses [30].

In general, mandibular prostheses that attach to implants have been shown to be highly satisfactory to patients, providing them with significantly improved function and comfort [31-44]. Early studies focused on mandibular prostheses that required 4-5 implants. However, more recent work has shown that patients benefit greatly from less costly prostheses on only two implants; these perform significantly better than the most carefully made new conventional dentures [31,45-49].

Nutrition is an important factor in many disease processes [50]. A Canadian advisory group of four people representing different disciplines: physiology,

family medicine, geriatrics, nutrition and dietetics - prepared a review on nutrition in the elderly and the role of nutrition as an important determinant of healthy aging. Those experts indicated that patients who have obvious nutritional problems are likely to suffer more disability and are at greater risk of premature death than elderly patients without nutritional problems. Therefore, the important role of nutrition in regulation of physiologic functions justifies attention to the role of dietary factors in both prevention and management of common geriatric problems [51]. Results from the SENECA study, a longitudinal survey in 8 European countries on nutrition and the elderly, clearly shows that healthy food habits are an important component of successful aging [52]. Furthermore, it is now recognized that malnutrition associated with poor oral health is also associated with physical impairment in older people [53].

Several studies have linked tooth loss to systemic disease in the elderly. Using data from a recent study (the Scottish Health Survey) using a national population sample of 12,871 adults, Watt et al. found that being edentate was an independent predictor of total cardiovascular disease mortality [54]. Abnet et al. used a cohort of 29,584 healthy, rural Chinese adults and found that tooth loss significantly increased the risk of death from any cause, as well as death from upper gastrointestinal (GI) cancer, heart disease, and stroke [55]. In a case-control study, Tosello et al [56] found that elderly institutionalized individuals with natural teeth had significantly fewer GI disorders than those wearing dentures. Hamasha

et al. [57] carried out a cross-sectional study on 175 elderly institutionalized men and women. They found that the prevalence of atherosclerotic vascular disease, heart failure, ischemic heart disease and joint diseases were significantly greater in the edentulous group. Joshipura et al. [58] hypothesized that the one-gram difference in fibre intake they observed between edentulous and dentate health professionals in the United States could result in a 2% increase in risk of myocardial infarction in the edentulous population. Results of another prospective study in a large population of elderly Japanese subjects strongly suggest that deterioration of general health occurs most rapidly in those with the fewest teeth, and that death occurs earlier [59].

Based on the results of these previously mentioned investigations and many others, some of which are presented in the introduction section of the included research manuscript, there certainly exists reason to be concerned that tooth loss and subsequent changes in diet increase morbidity and probably the risk of mortality in the elderly. Thus, it is important to find an answer to the question: *does treatment with simple mandibular implant overdentures improve the nutritional state of elderly edentulous Canadians?* If we find that individuals with prostheses retained by two implants have a better nutritional state than those with conventional dentures, this could then be translated into recommendations on standard of care for the millions of elderly Canadians who are missing all of their teeth.

1.3 Background of Current Analysis

In 2003, Morais et al. [60] published the findings of an RCT that measured the nutritional status of 56 healthy, independently-living edentulous elders wearing mandibular two-implant retained overdentures and conventional dentures at 6 months post-treatment (CD=27: F=17, M=10; IOD=29: F=15, M=14) from Montreal, Canada. Those assessments were done by means of three-day food records, blood parameters, and anthropometric measurements. Significant improvements in anthropometric parameters were detected in the IOD, but not in the CD group. Significant increases were also seen in concentrations of serum albumin, hemoglobin, and B12. However, the evaluation of nutrient intake by means of food diaries yielded no significant between-group differences. Morais et al. then suggested that the food diaries used in that study might have been insensitive because of the small sample size and, thus, their findings required confirmation. Therefore, a larger randomized clinical trial began, in which the sample size was increased for adequate power to carry out a definitive analysis of the nutritional outcomes. The first report from this RCT was the topic of a PhD dissertation published in 2008 [61]. It aimed to measure the impact of mandibular two implant overdentures on the general and oral health quality of life, as well as on oral health and sleep quality of edentulous elders. The second report aimed to determine whether providing simple mandibular IODs to elderly individuals

would give them a significantly better nutritional profile than those who receive CDs [62]. The primary outcome for that analysis was blood serum concentration of homocysteine (tHcy). Secondary outcomes included blood concentrations of folate, vitamin B6, vitamin B12, C-reactive protein (CRP), and albumin. Moreover, level of difficulty associated with chewing foods of various textures was presented. Additionally, using data from the same RCT, Michaud et al. [63] published the results of a study that evaluated the level of association between patients' denture satisfaction and oral health-related quality of life (OHRQoL) in edentate patients and identified the determinants of satisfaction that best predict OHRQoL. The effects of time and treatment type were also assessed.

This Masters thesis provides an analysis of the dietary intake differences between the IOD and CD groups that might not have produced significant changes in the blood nutritional profile, as reported by Awad et al.. These findings are reported in this thesis that also includes a research manuscript that has been submitted for publication to the Journal of Dental Research.

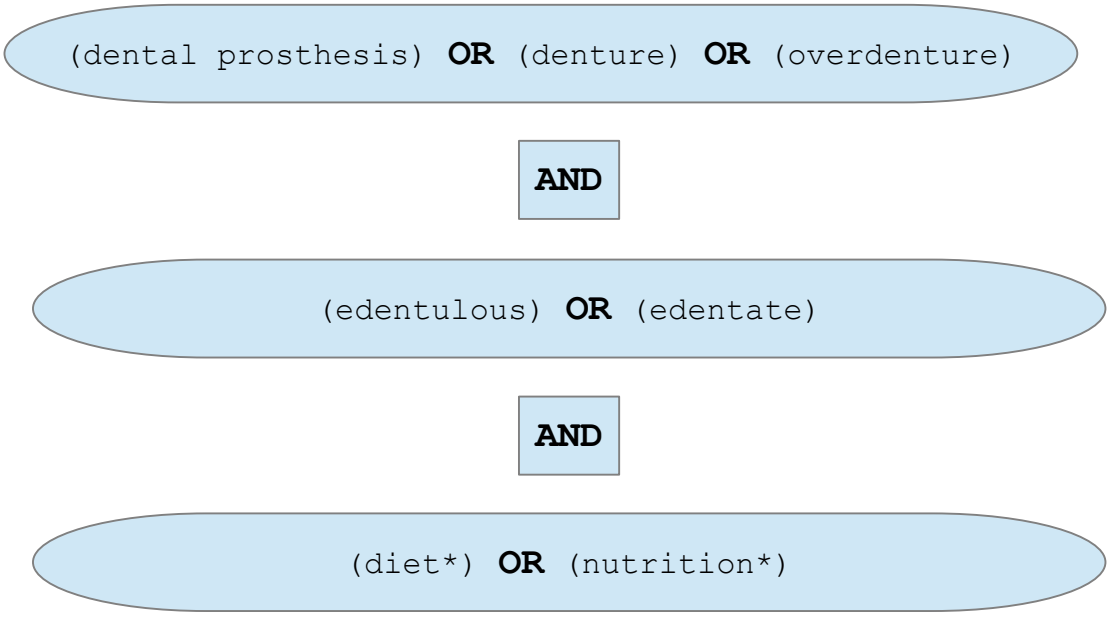
CHAPTER 2

THE LITERATURE REVIEW

A man who reviews the old so as to find out the new is qualified to teach others.
– Confucius

2.1 Literature Search Strategy:

In order to review the most pertinent scientific literature available, thorough searches of twelve online bibliographic databases were performed. The search was limited to English language and covered evidence as far back as what is electronically available until the 27th day of March 2013. The following search keywords were used:



A hand search of bibliographies of all included studies and identified review articles was also performed.

- 1009 publications in total
- 574 items after automatic removal of duplicates.
- 96 publications after reviewing the titles and abstracts and manual removal of duplicates.
- **55** peer-reviewed articles included after reviewing the full content.

Table. Literature Search Details.

	Database	**Date range**	**Quantity**
1	Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R)	1946 to Present	110
2	BIOSIS Previews	1969 to 2013 Week 13	14
3	Web of Science	All Years	89
4	Embase Classic + Embase	1947 to 2013 February 27	94
5	Pubmed	AFAEA*	138
6	Scopus	All Years	154
7	CINAHL Plus with Full Text	AFAEA*	23
8	The Cochrane Library (All)	AFAEA*	15
9	Ovid HealthSTAR	1966 - January 2013	104
10	Global Health	1973 - January 2013	16
11	ProQuest Dissertations & Theses (PQDT)	1959 - 2012	170
12	ProQuest Research Library	AFAEA	82

*AFAEA = As far as electronically available.

2.2 Literature Review Strategy

Based on the results of the search, 55 peer-reviewed articles were chosen to be included in this review. A decision was made to retain all studies, with different methodologies, in order to thoroughly cover all aspects related to the topic of

this thesis. However, the design, sample size and other relevant information from each of these studies will be highlighted in order to illustrate the strength of evidence each represents. Clear boundaries between some of those articles cannot be easily established, as some discuss more than one aspect of aging and its relation to nutrition with or without a dental prosthesis. However, after revising those reports, they were grouped under four major subheadings based on their main objectives:

1- Old age and nutrition.

2- Dental prostheses, dentition status and nutrition

3- IOD: The first standard of care – Consensus reports.

4- CD, IOD and nutrition.

2.2.1 Old Age and Nutrition:

Nine articles aimed to study or report the relationship between old age and nutrition (Appendix, Table APP1).

Does old age intrinsically predispose to nutritional deficiencies?: As people become older, they develop special nutritional requirements and acquire dietary habits consequent to changes in physiology, metabolism and function that accompany the aging process. This puts elders at increased risk of various nutritional deficits [64,65]. A recent cross-sectional study aimed to determine the risk of malnutrition in both institutionalized and non-institutionalized elderly

people in the region of Murcia in Spain [66]. It was found that there were no significant differences in terms of malnutrition or the risk of malnutrition between the participants with or without dentures or between the dentate or edentulous participants. Still, a greater prevalence of malnutrition was recorded in the older and in the institutionalized participants, implying that old age, rather than dentition status was the main risk factor of malnutrition in the elderly. However, all other reports [67-72] did not agree with those findings. Pirlich and Lochs [69] emphasized that aging itself does not lead to malnutrition. Malnutrition in elderly people is a consequence of somatic, psychic or social problems. Amongst the typical causes are chewing or swallowing disorders. Three Japanese studies [67,68,71] followed to support the findings of Pirlich et al.. Ikebe et al. [67] used a sample of 850 elders to investigate the effect of ageing, occlusal support and TMJ condition and general health status on bite force in older adults. They indicated that the reduction of bite force is not a natural effect of ageing, since tooth loss is not physiologic, but pathologic, ageing. Elders can still guarantee good masticatory ability with increasing age by maintaining a reasonable number of healthy natural teeth. Those results were supported by the study of Wakai et al. [71] who used a large sample of dentist members of the Japanese Dental Association as subjects (n=20366; F=1629, M=18737). Data were analyzed from an ongoing cohort study, named LEMONADE (Longitudinal Evaluation of Multi-phasic, Odontological and Nutritional Associations in Dentists). The mean intakes

of some key nutrients and food groups, such as carotene, vitamins A and C, milk and dairy products and vegetables, including green-yellow vegetables, decreased with the increasing number of teeth lost. This shows that tooth loss is linked with poorer nutrition, even amongst dentists, for whom sufficient dental and medical care is available. Consistent with this, Kikutani et al. [68] recently conducted a large-scale cross-sectional survey in eight cities in Japan in a sample of 716 (F=476, M=240). This survey aimed to determine the risk of malnutrition in some Japanese communities in which the frail elderly receive public long-term care insurance. The relationship between nutrition status and dental occlusion was evaluated using logistic regression analysis with sex, age, activities of daily living and cognitive function as covariates. Kikutani et al. concluded that the loss of natural tooth occlusion is a risk factor for malnutrition amongst community-dwelling frail Japanese elders. Retaining natural teeth plays an important role in the prevention of nutritional disturbance. Likewise, Osterberg and Steen [72] published their findings from a cross-sectional investigation that was part of a geriatric population study in Goteborg, Sweden. Their analysis found that insufficient intake of some nutrients was significantly related to the degree of dental invalidity, as measured with Eichner's index. Lower intakes of most nutrients in edentate people (compared with those with teeth) were also reported in a sample of independently living elders who were part of the British National Diet and Nutrition Survey (NDNS) [70].

2.2.2 Dental Prostheses, Dentition Status and Nutrition:

Out of the 55 publications included, 25 articles described research on the complex interrelationships between dental prostheses, dentition status and nutrition (Appendix, Table APP2).

Does the loss of natural dentition followed by the use of a CD compromise nutrition?: In 1983, Wayler and Chauncey reported that the mean masticatory performance scores were significantly lower for persons with CDs than for individuals with intact, partially compromised, or compromised dentition [73]. Many studies followed to confirm their findings [74-79]. Krall et al. [79] conducted a 2-year prospective observational study to evaluate the intake of specific nutrients among partially or completely edentulous groups of middle-aged and elderly men. The secondary aim of this study was to examine the relationship of masticatory function to nutrient intake. It was found that dentition status and nutrient intakes were significantly related to masticatory function. Krall et al. then concluded that the prevention of tooth loss and prosthodontic replacement of missing teeth could help people maintain a healthy diet. In the same year, Papas et al. [78] published the results of a cross-sectional study to determine of whether dentate status and other oral parameters were predictive of nutrition variables. They found that the introduction of dentures could further compromise the precarious nutritional intake of the elderly population. Thus, they recommended

that dentists carefully consider the importance of their elderly patients maintaining at least some natural dentition and to provide denture wearers with adequate information on nutritional adaptation to dentures. Mishellany-Dutour et al. [76] found that edentate elders with complete removable dentures make significantly more chewing strokes before swallowing than dentate elders and that food particle size reduction is significantly poorer. Their inference was that masticatory function may adapt to ageing, but is classically impaired in denture wearers. Nowjack-Raymer and Sheiham [77] analysed data taken from a cross-sectional survey in a representative sample of the US adult population using a stratified, multi-staged, probability sample design . They tested whether the intake of specific nutritious food items and dietary fiber differed between those who were edentulous wearing complete upper and lower dentures (n=1373) and those who had all of their natural teeth (n=2421). Over an evaluation period of six years, they found that the intake of some nutrient-rich foods, carrots, tossed salads and dietary fiber, as well as serum levels of beta carotene, folate, and vitamin C, were significantly lower among denture-wearers. Similarly, Cousson et al. [74] conducted a prospective comparative clinical study to determine whether a group of French elderly complete denture wearers (n=97) have a higher risk of malnutrition than dentate controls (n=47). Based on their between-group comparison of Mini Nutritional Assessment (MNA) scores, Cousson et al. showed that more participants in the edentulous group (21.3%) risked malnutrition than

in the dentate group (0%). This suggests that the use of conventional dentures increases the risk of malnutrition in the elderly edentulous as compared with dentate individuals. However, using a small sample of 72 subjects, Greksa et al. [75] indicated that, although edentulous patients were more likely to claim that they had trouble chewing their food, they were not more likely to select easy-to-chew foods. On the other hand, the diet of dentate people tended to be superior to that of edentulous individuals, as indicated by a lower fat and cholesterol consumption and a higher consumption of protein and all of the measured vitamins and minerals. They then concluded that tooth loss and denture wearing are not associated with a change in dietary patterns, but are associated with a decrease in dietary adequacy.

Does providing the edentulous with a new CD, with or without dietary counselling, or improving the technical quality of their existing CD improve nutrition?: Baxter [80] measured the dietary intake of 18 nutrients through 4-day dietary intake diaries. He indicated that the actual nutritional intake of the 23 patients (F=13, M=10) followed up for 3 months did not improve as much as expected after fabrication of their new CDs. However, their psychological results were better than expected. Baxter reported that getting the geriatric patient to maintain a good diet is not always easy, as environmental factors such as low economic status and ingrained eating habits influence their food selection. Many years later, P.F. Allen [81] reached similar conclusions using pre- and post-treatment

validated questionnaires to assess the impact of CD treatment on OHRQoL, diet and ability to chew food in an Irish population of independently-living edentulous elders. Food selection among the 35 subjects (F=23, M=12) who provided baseline and 2 months data was not ideal and not improved by the provision of new CDs. There was no association between diet and OHRQoL. Although most of the subjects had control over preparation of their own food, their diet was still lacking in fruit, vegetables and fibre. Allen suggested that further efforts are required to promote a healthy diet in older adults' age group and that it must not be assumed that this will occur spontaneously following provision of new dentures. Those findings were also supported by Papas et al. [82] who conducted a Nutrition and Oral Health Study (NOHS). They concluded that, with the many challenges facing elders, they cannot be relied upon to make dietary adaptations on their own without the guidance of caregivers responsible for oral health. All elderly dental patients, particularly those with less education, should be provided with the appropriate dietary guidance to allow them to adapt effectively to dentures. Two years later, Budtz-Jørgensen et al. [83] reviewed the literature to look at the possible advantages of rebuilding the dentition in older adults, primarily from the point of view of masticatory function and nutrition. They found that masticatory function impaired because of tooth loss or wearing of ill-fitting dentures will normally improve following prosthetic therapy. This might have implications for food choices, oral comfort and quality of life. However, an

impaired masticatory function does not systematically give rise to a deficient nutritional status. Thus, there is no evidence that the provision of prosthetic therapies can markedly improve dietary intakes even if it improves oral comfort and quality of life. Similar findings were reported by Shinkai et al. [84], Bradbury et al. [85], Wostmann et al. [13] and Gunji et al [14]. Shinkai et al. [84] conducted a cross-sectional study on 54 participants (F=28, M=26) to investigate the relationship of complete denture quality to masticatory performance, perceived ability to chew and diet quality as measured by the Healthy Eating Index (HEI), an overall diet quality index. They concluded that complete denture quality and perceived chewing ability were not related to quality of a diet. The majority of subjects had deficient diets, regardless of the technical quality of their dentures. This suggested that the provision of technically perfect dentures is not of primary importance to diet quality. Shinkai et al. stated that, to improve the complete denture wearers' diet, an interdisciplinary approach with referrals to a nutritionist and/or physician should be considered. In 2008, Wostmann et al. [13] published similar conclusions from an exploratory interventional clinical study on 34 (F=21, M=13) subjects from two nursing homes in Germany. They aimed to identify the impact of denture improvement on nutritional status, as well as the oral health-related quality of life in those geriatric patients who were capable of feeding themselves and with dentures requiring repair or replacement. After 6 months, those investigators found that, despite the highly significant

improvement in masticatory ability after the repair/restoration of the dentures, no general improvement regarding the nutritional status was observed, since the albumin, zinc and MNA values remained unchanged and pre-albumin even decreased. Wostmann et al. then concluded that nutrition is not only a matter of masticatory function, but that it also depends on other factors, such as habits, taste and cultural customs, as well as financial and organisational aspects. Bradbury et al. [85] conducted a study to determine if perceived chewing ability was predictive of fruit and vegetable intake, to explore the predictive ability of knowledge, attitude, and self-identity and to compare intake between edentulous and dentate individuals. They found that perceived chewing ability amongst 131 participants (CD= 79: F=52, M=27; Dentate= 52: F=27, M=25) explained only about 4% of the variance in fruit and vegetable intake. In contrast, psychosocial factors, particularly the presence of a positive attitude, had a much greater impact, explaining around 20% of the variance. Improving perceived chewing ability through prosthetic rehabilitation may not improve fruit and vegetable intake in the absence of contemporaneous intervention to address psychosocial factors. Those findings were based on a cross-sectional study that used a relatively small sample size. However, Kagawa et al. [86] conducted a study using the same design but with a much bigger sample (n=1,535; F=714, M=821) and obtained similar findings. They hypothesized that perceived masticatory ability would be more relevant to dietary intake than tooth loss or wearing dentures.

Their multivariate analyses showed, after adjusting for age, sex, and financial status, that self-assessed masticatory ability, and not dental status, was significantly associated with shortages in vegetable and fruit intake in independently living elderly Japanese subjects. Gunji et al. [14] carried out a matched-pairs clinical study on 30 (F=13, M=17) Japanese elders to investigate changes in diet and nutrient adequacy between complete denture wearers with their existing dentures and those with new dentures. They found that, though self-evaluation of masticatory function improved after the switch from old to new dentures, the two groups were similar in the total intake of energy and nutrients. However, just one year following this study and again from Asia, another study presented contradictory results [87]. Lin et al. conducted an observational study to analyze 24-hour dietary intake data from 103 (F=35, M=68) Taiwanese participants. They found that patient satisfaction with the comfort of their dentures during mastication significantly impacted the diet (quantity and quality) of these elderly edentulous patients. This was also shown in the study of Sahyoun and Krall [88] that used data from 1,613 complete denture wearers aged 50 years and older who participated in the third US National Health and Nutrition Examination Survey (NHANES III), a nationally representative, cross-sectional survey. The authors concluded that dietary quality and intake of certain nutrients was poorer in the group with self-perceived ill-fitting dentures than amongst those wearing adequate dentures or with natural teeth. Similarly, Lamy et al. [89]

conducted an observational study in Belgium to evaluate, in an institutionalized elderly population, whether poor oral status is a contributing factor in the development of under-nutrition. The nutritional assessment part of that study included serum albumin concentration, MNA scores and a questionnaire on eating habits. It was found that the institutionalized edentulous subjects without dentures or with only one CD had significantly lower MNA scores than edentulous subjects wearing two CDs ($p < 0.05$). Subjects with two CDs had similar or better MNA scores as dentate subjects with relatively few remaining teeth (10.4 ± 7.8 teeth). Thus, poor oral status (edentulous without dentures or with only one CD) not only increased difficulty in eating hard foods and decreased eating pleasure, but it seemed also to put institutionalized subjects at higher risk of under-nutrition. In the same year, Mojon et al. [90] published a cross-sectional study with the similar aim to evaluate the relationship between oral health status and nutritional deficiency in institutionalized frail elders. It was reported that among the edentulous (49% of 324 participants), wearing dentures with defective bases or not wearing dentures at all were the factors most associated with malnutrition. In a more recent cross-sectional study [91], the investigators aimed to determine whether oral status with emphasis in edentulism and complete denture use was associated with the daily consumption of the recommended amounts of fruit and vegetables in south Brazilian community-dwelling older people. It was found that edentulous participants

wearing only one denture were less likely to consume at least 400 g per day of fruit and vegetables; thus, having some natural teeth or wearing two CDs in case of edentulism may have a beneficial role on consumption of the recommended amount of fruit and vegetables. Further support to this finding came from two Indian studies reported in three articles. The first was a pilot comparative clinical study [92] to assess changes in the nutritional health of elderly adults before and one month after placement of dentures in completely edentulous individuals. Shigli et al. concluded that prosthodontic rehabilitation with CDs of edentulous patients improved the eating pattern, with increased intake of fruits, vegetables and milk products. In the other clinical study, with a matched-pairs design [93,94], the nutritional status of 94 healthy edentate elders was assessed using the MNA at baseline and 6 and 9 months following treatment with CDs. This study found that the edentulous patients without CDs had significantly lower MNA scores that put them at higher risk of malnutrition. Prosthetic rehabilitation of edentulous patients with CDs, along with dietary counselling, improved the nutritional status of these patients. Patient education and nutritional counselling created awareness of nutritional problems amongst the patients, which led to an increase in the consumption of vegetable soups, fruits and juices. Whether tailored dietary intervention has a positive impact on dietary behavior of patients receiving replacement CDs was the main question in the study of Bradbury et al. [95]. In this RCT, all participants were CD wearers. The intervention group (n = 30)

received two dietary counselling sessions, while the control group (n = 28) received standard care. It was found that tailored dietary intervention concurrent with replacement of dentures can positively change dietary behavior.

2.2.3 IOD: The First Standard of Care – Consensus Reports:

Four articles reported or followed up on two consensus statements advocating IODs as the first choice standard of care for edentulous patients (Appendix, Table APP3).

In 2002, Feine et al. [96] published the first independent consensus report that was prepared to reflect the knowledge from published studies, expert opinions and patient experiences accumulated until 2002 in regards to adopting the IOD on a minimum of 2 implants as the first choice of treatment for the edentulous mandible. The report was based on consensus agreement amongst experts from different parts of the world who work in areas relevant to the consensus question, available scientific knowledge on the topic and personal experience of the patients/ participants. It was stated that the evidence available at that time suggests that the restoration of the edentulous mandible with a conventional CD is no longer the most appropriate first choice prosthodontic treatment. There is now overwhelming evidence that a 2-implant overdenture should become the first choice of treatment to restore an edentulous mandible. Seven years later, another report was published to reflect the consensus agreement among

presenters at the Annual Conference of the British Society for the Study of Prosthetic Dentistry (BSSPD) that was held in York, UK. They offered a synopsis of the latest research available on the efficacy of IODs in the edentulous mandible, the view of the council members of the BSSPD and opinion of BSSPD members on the Society's website [97]. Consensus agreement among those professionals stated that the evidence suggests that the restoration of the edentulous mandible with a conventional CD is a much poorer alternative than the use of an IOD. A large body of evidence supports the proposal that a two-implant supported mandibular overdenture should be the minimum offered to edentulous patients as a first choice of treatment. In 2012, Das et al. published the results of a Delphi method survey of academic prosthodontic experts [98]. This survey was conducted to determine if, in 2011, U.S. academic prosthodontic experts' opinions were aligned with those in the two previous consensus statements, McGill (Canada 2002) and York (England 2009). Consensus agreement was defined as a 70 percent agreement level among the 16 nationally representative academic prosthodontists. The panel attained consensus favouring the IOD for nine of the 10 parameters assessed - retention, stability, speech, masticatory efficiency, comfort while eating soft foods and hard foods, confidence in intimate situations, satisfaction and self-esteem. The exception was esthetics, for which only a majority (51-69 percent) favoured the IOD. The surveyed academic prosthodontists then reached consensus that they would recommend an IOD,

instead of a CD, as the first-choice standard of care for patients who are healthy or have mild systemic disease, but not for patients with severe systemic disease. Also in 2012, Thomason et al [99] reviewed the literature to present the 2012 evidence and rationale to support the McGill and York consensus statements. The review found that there were sufficient studies, using satisfaction and OHRQoL outcomes, to demonstrate that the evidence consistently points to real advantages of IODs for rehabilitation of the edentulous mandible compared to CDs. The evidence supports the McGill and York consensus statements. The review also indicated that whilst it is accepted that the two-implant overdenture is not the gold standard of implant therapy, it is the minimum standard that should be sufficient for most people, taking into account performance, patient satisfaction, cost and clinical time. The reviewers then declared that the next task is to identify and overcome barriers for the delivery of this care for the benefit of edentulous patients.

2.2.4 CD, IOD and Nutrition:

Seventeen articles reported on the relationship between IODs, CDs and nutrition (Appendix, Table APP4).

Are IODs more retentive and do they provide better masticatory performance than CDs?: Neto et al. [100] published the findings of an RCT that aimed to evaluate the masticatory efficiency of healthy, independently living Brazilian elders

rehabilitated with conventional CDs or IODs retained by two splinted implants with bar-clip system. They used a small sample size (total n=29; n=15 CD, n=14 IOD) and followed up participants for only 3 months after denture insertion. Nevertheless, they reported that the mandibular overdentures significantly improved patients' chewing experience and retention. Still, there was no significant difference between the two groups in masticatory efficiency when evaluated using the colorimetric method with beads as the artificial test-food. However, a within-subject cross-over clinical trial that followed up a group of 18 healthy Dutch elders for 14 months [101] revealed that both masticatory function and chewing experience significantly improved after implant treatment. This positive improvement was true, regardless of the attachment type used with the two implant-retained overdenture.

Is there any evidence that improved masticatory function leads to better nutrition with IODs?: de Oliveira and Frigerio [102] conducted a cross-sectional study on 40 (CD=23, IOD=17) participants to assess the possible risk of malnutrition among the elderly population. It was found that patients wearing mandibular IODs were considered well nourished (76.47%) when compared with CD users (43.48%). There was a significant difference between the two groups concerning chewing ability and nutritional status. It was then concluded that CD users can be more susceptible to malnutrition when compared with IOD users. De Oliveira and Frigerio suggested that this may be because of the increased

ability to chew different types of food in the IOD group and that the psychological condition of the elderly should also be considered, as it influences the interest in diet and choice of food. Another matched-pairs clinical study using a smaller sample size (n=16) supported the findings of de Oliveira and Frigerio [103]. Borges et al. aimed to compare masticatory performance and the nutritional condition of CD wearers before and after conversion of the lower prosthesis into an IOD retained by two implants with an immediately loaded bar-clip, as well as the association between masticatory performance and nutritional condition. Participants were assessed at baseline and at 3 and 6 months post-treatment. It was found that the masticatory performance test, using an artificial test food after forty chewing strokes, demonstrated a statistically significant difference before (baseline) and 3 and 6 months after changing the lower CD to an IOD. A statistically significant difference before and after 6 months for nutritional condition, evaluated using an MNA questionnaire, was also observed. Borges et al. then concluded that the increased retention of the mandibular prosthesis enabled improvement in masticatory performance, as well as nutritional state.

Is there evidence that IODs and CDs result in similar dietary intake if nutritional counselling is not provided?: Contrary to the findings of the two Brazilian studies, de Oliveira and Frigerio [102] and Borges et al. [103], all other reports [60,62,104-112] confirm that the superior masticatory function with IODs over CDs does not translate into better nutrition when not supplemented with dietary counselling.

In 1987, the first study to look at nutritional differences between IOD and CD wearers was published. Sandstrom and Lindquist [109] conducted a prospective comparative clinical study on 23 Swedish participants to analyze the long-term effects on dietary habits and food selection before, during, and after restoration of masticatory ability. This was achieved by optimizing the CDs or inserting mandibular IOD prostheses. Following verbal and written directives and using household measures, the subjects recorded intake of food and drink during 4 consecutive days. The first record was obtained before treatment, the second about 2 months after treatment with optimized CDs, and the third to seventh recordings were carried out 2 to 70 months after rehabilitation with IOD prostheses in the lower jaw. The results of this study indicated that, even after treatment with IODs and more or less complete restoration of masticatory function, the spontaneous change in dietary habits was small and had only marginal nutritional effects. Thus, Sandstrom and Lindquist suggested that an improved oral function will not, in itself, lead to a change in dietary selection and that dietary changes probably require professional and individually given dietary advice by a trained dietician. Eight years later, using the same study design, but with a larger sample size (n=71), Sebring et al. [110] supported the findings of Sandstrom and Lindquist. They found that there were no significant differences in intake of calories or of 27 nutrients between two groups of edentulous individuals who received either new IODs or new CDs. Those findings were based

on data from food records gathered 3 days before treatment, 2 months after, and then semi-annually for up to 3 yrs. In 2001, Hamada et al. [106] published the results of the first RCT to compare dietary intake of mandibular IODs and conventional CDs. They compared the pre- and post-treatment diets of edentulous controlled diabetic patients who received new dentures with either a conventional CD or a mandibular IOD supported by 2 cylindrical implants connected with a Hader bar. They used a sample size of 58 (CD=21; IOD=37) participants who submitted a dietary log for 7 consecutive days before treatment and 6 months after treatment completion. Hamada et al. found that the replacement of old mandibular CDs with new CDs or IODs did not lead to an improvement in the dietary intake of essential micronutrients and macronutrients. This was true for all participants with acceptable metabolic control of diabetes, whether the metabolic control was maintained with or without insulin. Allen and McMillan [111] conducted an RCT to assess whether changes in food selection and in perceptions of chewing ability occurred in edentulous patients following the provision of implant and conventional prostheses. Validated pre- and postoperative questionnaires were used to measure food selection and chewing ability among participants at baseline and 3 months later. It was found that, despite the reported improvement in satisfaction with comfort and ability to chew food, 30–50% of participants who requested and received implants to stabilise a complete fixed or removable prosthesis

(n=26) and edentulous participants who requested and received conventional CDs (n=35) still avoided eating foods such as carrot and apple. Allen and McMillan suggested that, in the absence of tailored dietary advice, apparently successful prosthetic rehabilitation does not necessarily result in a satisfactory diet. Another RCT provided more extreme evidence on the possible importance of dietary counselling [112]. Roumanas et al. used one-week dietary logs and a 10-point chewing difficulty scale to rate food items in the dietary logs to determine whether chewing difficulty of consumed foods is altered by the replacement of existing CDs with a maxillary denture and either a mandibular CD or an IOD retained by two implants connected by a Hader bar. Fifty-eight (CD=21, IOD=37) elders with controlled diabetes, managed with or without insulin, provided data at baseline and 6 months post-treatment. The authors found that, with original dentures, more than 91% of subjects consumed foods with chewing difficulty scores of 6 to 10 at least seven times per week. However, with the new study dentures, only 21% maintained this level of consumption, with the frequency decreasing to four to six times per week in 24% and one to three times per week in 43% of subjects. The declines in consumption frequency of more difficult to chew foods with the new dentures were in a higher percentage of subjects in the implant than in the conventional group. Roumanas et al. concluded that, after 6 months of adaptation to new dentures, patients consumed fewer difficult-to-chew foods than with their original dentures. This decline was more frequent

with mandibular IODs than with conventional CDs. It was then recommended that dietary counselling should be considered as part of implant and complete denture therapy. The first RCT in Canada to look at the same topic was that of Morais et al. [60]. Using a sample of 56 (CD=27: F=17, M=10; IOD=29: F=15, M=14) healthy, independently living elders, Morais et al. tested the null hypothesis that there is no difference in nutritional status between patients with mandibular two-implant retained overdentures and those with conventional dentures at 6 months post-treatment. The nutritional state of participants was assessed by means of three-day food records, blood parameters, and anthropometric measurements at baseline and 6 months post-treatment. Morais et al. detected significant improvements in anthropometric parameters in the IOD, but not in the CD, group. The IOD group showed significant increases for percent body fat ($p = 0.011$) and skin-fold thickness at the biceps ($p = 0.023$), subscapularis ($p = 0.013$), and abdomen ($p = 0.005$), with significant decreases in waist circumference ($p < 0.0001$) and waist-hip ratio ($p = 0.001$). Significant increases were also seen in concentrations of serum albumin, hemoglobin, and B12. However, the evaluation of nutrient intake by means of food diaries yielded no significant between-group differences. Morais et al. then suggested that the small sample size used did not provide adequate power for the nutritional outcomes, and whether or not IOD treatment improves the nutritional state of edentulous people should be confirmed in an adequately powered study. In 2008, two more articles to support

those previous findings were published [104,107]. Muller et al. [107] used a cross-sectional design to evaluate the nutritional status of 53 healthy, independently living denture wearers, edentulous for >10 years and who had randomly received either a CD or an IOD one year previously. It was then reported that the body composition indicators as well as plasma parameters were generally within normal range, and no statistically significant difference was found between the groups. Patients in the CD group had significantly lower ratings for items regarding difficulty in chewing, but no significant difference was found for dietary intake. Muller et al. then concluded that although the CD wearers reported having more difficulty in chewing hard foods, both the CD and the IOD groups appeared to have a similar nutritional status. Ellis et al. [104] conducted an RCT to compare food choices of 97 edentulous UK elders provided with IODs and conventional CDs. Subjects indicated whether they consumed any of seven test foods and the level of chewing difficulty experienced using a previously validated questionnaire. Data were collected pre-treatment and 3 months post-treatment. Ellis et al. found that food selection and perceived chewing difficulty improved in both groups, with no significant differences between groups and that successful rehabilitation may not result in different food selection, which may require concurrent tailored dietary interventions. In 2010, Sanchez-Ayala et al. [108] conducted a systematic review on this topic of all relevant studies that used valid scientific methodologies. After searching several electronic databases, they

included clinical trials using anthropometric or nutrient intake measurements of CD and IOD denture wearers. The authors concluded that any pre to post-treatment effect on the nutritional state of IOD wearers is similar to that obtained from CD wearers. This effect does not necessarily mean an optimum nutritional state, which also depends on psychological and sociocultural factors not related to prosthodontic treatment. Two more RCTs published in 2012 reached the same conclusions [62,105]. Awad et al. [62] reported the primary outcome as well as some of the secondary outcomes of the same RCT that is the subject of the masters project reported in this thesis. This RCT included a sample size of 255 (CD=128: F=71, M=57; IOD=127: F=70, M=57), which is the largest reported so far. The objective of Awad et al. was to determine whether providing simple mandibular IODs to healthy, independently living elderly individuals would give them a significantly better blood nutrient profile than those who receive conventional CDs. The primary outcome was blood serum concentration of homocysteine [tHcy], which is a marker of general health sensitive to changes in dietary intake of fresh fruits, vegetables, and meats. Blood concentrations of folate, vitamin B6, vitamin B12, C-reactive protein (CRP), and albumin were also reported as secondary outcomes. Moreover, participants completed a Likert scale questionnaire to rate level of difficulty associated with chewing foods of various textures. Awad et al. stated that clinically important differences in blood nutrients and health parameters were not observed between the CD and the IOD

groups at baseline, 6 months and 12 months post-treatment. However, IODs wearers had significant improvement in ability to chew and food habits. Gjengedal et al. [105] compared the dietary intake of two groups of edentulous elders dissatisfied with their existing mandibular dentures; one group had their CDs (n=26) conventionally relined, while the other (n=27) had their mandibular dentures converted into IODs. Three 24-hour dietary intake data were gathered at baseline, 4, 8, and 11 months after treatment, as well as self-administered demographic and food avoidance questionnaires at baseline and at 3, 6, 12 and 24 months after treatment. Consistent with findings from previous studies, Gjengedal et al. found no significant differences regarding food choices and nutrient intake between the IOD and CD groups. However, the IOD group reported significantly better chewing ability, less food avoidance, and greater willingness to eat more of certain food items.

Does tailored dietary advice really lead to differences in dietary intake between IOD and CD wearers?:

Following on the previous findings and recommendations, two studies aimed to compare the effectiveness of an individually tailored nutrition intervention provided to participants wearing either conventional CDs or IODs [113,114]. Ellis et al. [113] conducted a prospective clinical study and analyzed data provided by 54 (CD=26: F=18, M=8; IOD=28: F=20, M=8) participants. Before delivery of the dietary advice, there were no significant between- group differences for

satisfaction or oral health quality of life (OHRQoL) scores. At 6 months, following provision of individualised dietary advice, the IOD group showed significantly greater satisfaction than the conventional group for denture comfort, stability, and perceived chewing ability. The authors concluded that the delivery of customised dietary advice to edentulous patients impacts on their satisfaction with denture comfort, stability and chewing ability differently depending on the nature of their prosthesis. This re-evaluation of satisfaction occurs when edentulous patients challenge themselves to consume more fruits, vegetables and fibre-rich foods. The IOD group reported an increased level of satisfaction and perceived chewing ability, whereas it appeared that CD wearers may have had their awareness of the shortcomings of this sort of prosthesis awakened. Moynihan et al. [114] conducted a two cohort prospective parallel dietary intervention study to compare the effectiveness of an individually tailored nutrition intervention aiming to increase the intake of fruits, vegetables and fibre between 54 (CD=26: F=18, M=8; IOD=28: F=20, M=8) healthy, independently living patients wearing conventional CDs and patients with IODs. Both groups increased fruit and vegetable intake at 3 and 6 months following dietary intervention, but intakes between groups did not differ. Moreover, both groups showed improvements in serum antioxidant status, but the IOD group had significantly higher plasma antioxidant capacity post intervention than the CD group. It was inferred that dietary intervention benefits denture patients in both

groups. IOD patients showed moderately greater dietary improvements compared with conventional denture patients. Moynihan et al. recommended that these positive dietary effects be perceived as a considerable health benefit of this combined form of prosthetic rehabilitation and diet intervention.

In conclusion, it is generally believed that as the elderly lose their teeth they become more vulnerable to a host of diseases and related complications, including malnutrition. The provision of new prosthesis, whether a CD or an IOD, seems not to be, by itself, enough to help elders meet their dietary needs. This is true regardless of the technical quality of the prosthesis. However, two major drawbacks of all studies conducted to date is that they either followed up participants for a short period of time or that they used small sample sizes. Thus, the need for a well-designed and well-powered RCT that follows participants for more than six months was evident. This RCT, the topic of this master's thesis presented in the next chapter, is the first to satisfy those requirements.

CHAPTER 3

RESEARCH MANUSCRIPT

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Do Implant Overdentures Improve Dietary Intake?: A Randomized Clinical Trial

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Abstract

It has been shown that patients wearing mandibular two-implant overdentures (IOD) chew food with less difficulty than those wearing conventional complete dentures (CD). However, there is still controversy over whether or not this results in better dietary intake.

In this randomized clinical trial, the amounts of total dietary fiber (TDF), macronutrients, nine micronutrients and energy in diets consumed by IOD and CD patients were compared. Male and female edentate patients ≥65 yrs (n=255) were randomly divided into two groups and assigned to receive a maxillary CD and either a mandibular IOD or CD. One year following prosthesis delivery, 217 participants (CD=114, IOD=103) reported the food and quantities they consumed to a registered dietician through a standard 24-hour dietary recall method. The mean and median values of TDF, macro- and micronutrients and energy consumed by both groups were calculated and compared analytically. No significant between-group differences were found (ps>0.05). Despite quality of life benefits from IODs, this adequately-powered study reveals no evidence of nutritional advantages for independently living healthy edentate elders wearing two-implant mandibular overdentures over those wearing conventional complete dentures in dietary intake of TDF, macronutrients, nine micronutrients or energy at one year following prosthesis delivery. (International CT Registration#: ISRCTN24273915).

Introduction

A large percentage of our aging population is edentulous [115,116]. Population studies have shown that edentate people have poorer nutrition than those with teeth [117], as well as being more vulnerable to a host of diseases and health conditions [118]. Furthermore, findings from several studies suggest that number of teeth is a significant and independent risk indicator for mortality and that use of adequate dentures may reduce this risk [119,120]. Thus, the importance of a mandibular two-implant overdenture (IOD) cannot be overemphasized in light of the accumulating scientific evidence supporting its use as a first choice standard of care for elderly edentate patients [97,121,122]. A recently published report showed that a panel of experts in the field of prosthodontics from different parts of the United States support treatment with IODs over conventional dentures (CDs) [98]. This report followed up on the McGill [122] and the York Consensus Statements [97] that were produced following decades of research demonstrating the superiority of mandibular IODs over CDs for many variables, including oral health-related quality of life [39,123], patient satisfaction (function & comfort) [124,125], food avoidance [126], chewing ability [127] and food preparation [62]. Although there is a long list of scientific reports and randomized clinical trials (RCT) on the advantages of IODs over CDs, few studies have investigated the effect of IODs on dietary intake. Those had limitations, such as the use of relatively small sample sizes [114,116,126-128]

or having been restricted to male diabetic patients [106]. Thus, there is still controversy over whether or not edentate individuals wearing mandibular IODs gain better nutrition through diet than those wearing CDs. In fact, a look at the possible dietary differences between mandibular IODs and CDs becomes more essential in light of the increase in the percentage of the elderly population, longer life expectancy and an increased demand for better quality of life for the elderly. Moreover, accumulating evidence has shown a relationship between an increased intake of some macro- and micronutrients to a reduced risk of some diseases and health problems, such as cardiovascular disease, rheumatoid arthritis, pulmonary disease and certain types of cancer [118,120,129,130]

The main objective of this RCT was to assess the effects of mandibular IODs on the nutritional status of an edentate elderly population. The primary hypothesis of the RCT was that patients who receive mandibular IODs would have no significant difference in their blood serum concentration of homocysteine [tHcy] than those who receive CDs at 6 and 12 months post-treatment. This was reported in a previous publication [62]. The secondary objective and the subject of this report was to determine whether those independently living edentate elders wearing new mandibular IODs and CDs consumed in their daily meals different amounts of micro and macronutrients, as well as total dietary fiber (TDF) and energy. This outcome could indicate whether there was a difference between the

groups in dietary intake that had not yet made a difference in blood nutrient values.

The following null hypotheses were tested:

1- There is no difference between the two groups in the intake of TDF one year post-treatment.
2- There is no difference between the two groups in the intake of energy (KCal.) one year post-treatment.
3- There is no difference between the two groups in the intake of three macronutrients (Proteins, Fats, and Carbohydrates) one year post-treatment.
4- There is no difference between the two groups in the intake of nine micronutrients (Vitamins A, B6, B12, C, and D, as well as Thiamin, Riboflavin, Folate, and Niacin) one year post-treatment.

Materials & Methods

Study Design:

Data reported in this paper were gathered from a randomized, controlled, parallel trial comparing the effects of 2 types of mandibular prosthetic treatment (IOD and CD) in independently living edentulous elders in Montreal, Canada. The study was conducted at the MUHC-Royal Victoria Hospital (RVH) Clinical Investigation Unit (Montreal, Canada). The data used in this analysis were obtained at baseline

and 12 months following prosthesis delivery using a standard 24-hour dietary recall method.

The study protocol and informed consent documents were approved by the institutional review board at McGill University. All study participants gave their written informed consent. Participants were financially compensated for their transportation and parking costs.

Sample Size Estimation:

The sample size estimation was carried out to maintain adequate power to assess the primary and secondary outcomes, including those described in this report [62]. One hundred and four subjects per group will be required to ensure power of 95%, using a 2-sided test at a 0.05 level of significance for the primary outcome. We have targeted our sample size for a somewhat higher traditional power than usual in order to enhance power for secondary outcomes. In terms of secondary outcomes, this sample size provides 80% power with a type I error of 0.05 on all parameters, using a 2-sided test. We also anticipated 18% loss to follow-up. Accordingly, we adjusted our targeted baseline sample size to 127 per group.

Recruitment:

Recruitment and treatment allocation steps were described in a previous publication [62]. In general, potential participants were recruited through French and English advertisements in local papers. Once eligibility and consent had been

confirmed, treatment assignment was obtained by the research assistant from an independent randomization center using a computer-generated permuted block scheme. Varying block sizes were employed to preserve allocation concealment and reduce any potential selection bias.

Participants:

The sample population consisted of males and females (≥65 yrs) who had been edentate for a minimum of 5 yrs. Other inclusion criteria included adequate understanding of written and spoken English or French, as well as willingness and ability to understand the protocol and to give informed consent. Potential participants completed a medical history with questions about oral condition, general health and use of medications. They also completed questionnaires on function to assess their ability to understand and use the measures to be employed in the study. They were then examined by two calibrated clinicians. Patients were excluded if they had insufficient bone for placement of 2 implants in the anterior mandible, acute or chronic symptoms of TMD, systemic or neurologic disease that contraindicates implant surgery, any neoplasia diagnosed <5 yrs previously, a body mass index (BMI) <20 or >32 kg/m^2, and/or if s/he was taking dietary supplements, anti-neoplastic medication, phenytoin, or corticosteroids. As memory must be intact to provide accurate 24-hour dietary recall information, potential participants were excluded if they scored 24 or less

on the Mini-Mental State Evaluation.

The Intervention:

Maxilla: Both the treatment and the control groups received a maxillary CD fabricated in a standard manner.

***Mandible*: *Treatment Group*:** Participants randomized to the experimental group received a mandibular IOD on 2 implants with ball attachments (ITI, Straumann-048.242/243, Waldenburg, Switzerland) in the canine region of the anterior mandible. Standard post-operative procedures were followed. After a 3 month healing period, the participants received new dentures in both jaws, a maxillary CD and a mandibular IOD. ***Control Group*:** Participants randomized to the control group received a mandibular CD fabricated in a standard manner.

Dietary Assessments:

Three 24-hour detailed dietary recalls were collected through telephone interviews at baseline as well as 12 months after prosthesis delivery. Trained personnel used a structured template to collect information on dietary intake during the previous 24 hours [131]. The interviews were conducted on 3 separate occasions, twice on weekdays and once on a weekend. The dietary intake values for these recalls were used to calculate every participant's intake of TDF, macronutrients (proteins, fat, and carbohydrates), nine of the micronutrients (Vitamins A, B6, B12, C, and D, as well as Thiamin, Riboflavin, Folate, and Niacin)

and energy. These individual values were then used to calculate the mean daily individual intakes, as well as the mean and median intakes of both groups. The participants had already been trained at baseline on food serving portions and on how to calculate and report their daily food intake. To standardize computations and reduce the individual computational errors, the data collected were analyzed using nutrient values from the Canadian Nutrient File with the help of a specialized software from the McGill University Faculty of Dietetics and Human Nutrition (CANDAT, Godin London Inc., London, Ontario)

Statistical Analysis:

Due to the skewed nature of several of the study variables, medians were estimated as the measure of central tendency. Wilcoxon rank sum tests were used for bivariate comparisons of the various independent variables according to treatment received (JMP statistical software version 10; SAS Institute Inc., Cary, NC). Quantile regression models were used to estimate the conditional median of the dependent variables (post-treatment values of the micronutrients) between treatments, controlling for baseline values and gender, as they require no distribution assumption; these models are more robust to outlying observations of the predictor variables (Stata SE software version 10.1; StataCorp, College Station, Texas). *P* values ≤0.05 were considered statistically significant for all analyses.

Results

Two hundred fifty-five (255) participants were enrolled and randomly assigned to receive a maxillary CD and either a mandibular CD (n=128) or an IOD (n=127). Two hundred seventeen participants (n=114 CD, n=103 IOD) provided follow-up data at one-year post treatment and were included in this analysis (Figure 1). Loss to follow-up included illness, fear of surgery and/or lack of interest. At baseline, the groups were similar in age (CD mean 69.7±SD 4.6; IOD mean 70.5±SD 5.0) and gender distribution (CD, males N = 57 (44.5%), females N = 71 (55.5%); IOD, males N = 57 (44.9%), females N = 70 (55.1%); p= 0.95).

Our analysis failed to reject any of our four null hypotheses (ps> 0.36; Table 1), even with sex stratification (ps> 0.17; Table 2). No inter-group significant difference was found in intake of TDF (ps> 0.36; Table 1), energy (ps> 0.58; Table 2) or macronutrients, i.e. proteins, fats or carbohydrates (ps> 0.41; Table 2) at baseline and one year post-treatment. There were also no significant differences between the two groups for any of the nine examined micronutrients (Vitamin A, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Thiamin, Riboflavin, Folate, and Niacin) (ps> 0.13; Table 1).

A non-significant linear association was observed for the relationship between all dependent variables (TDF, energy, macro- and micronutrients) and treatment adjusted for baseline values and sex (Table 3). However a tendency for higher

median dietary intake values of energy, the three macronutrients (proteins, fats and carbohydrates), vitamin D, Thiamin, vitamin B6, vitamin B12 and folate among CD wearers was observed. Similarly, there was a tendency for higher median dietary intake values of TDF, vitamin A, vitamin C, riboflavin and niacin among individuals with IOD. Based on this regression model, females had significantly higher median dietary intakes of thiamin and riboflavin and significantly lower intakes of energy and folate after adjustment for treatment received and baseline values. Moreover, baseline median intakes of energy, protein, thiamin, and riboflavin were significantly higher, and baseline values for folate were significantly lower, after adjusting for treatment received and sex.

Discussion

To our knowledge, this is the first RCT that used an adequate sample size to study differences in dietary intake between IOD and CD wearers. The above results demonstrate that, one year after delivery of the new prosthesis, the dietary intake of healthy elders receiving a mandibular two-implant overdenture is not statistically different than that of those treated with conventional complete dentures. The two groups had similar intakes of TDF, energy, macronutrients (proteins, fats and carbohydrates), as well as nine of the micronutrients. Although our results support findings from previous studies [106,116,126,132], several limitations of this type of nutritional comparison should be mentioned. The bias

due to reporting error inherent in the twenty-four hour dietary recall method may be greater than the inter-group difference [133]. Moreover, the self-report of dietary intake could be biased by social desirability [134]. However, given the relatively large sample size used in this study and using the average value of three recalls, these 24-hour recall data are likely to be appropriate.

Furthermore, our results also raise a number of questions: First, why are the dietary intakes so similar in both groups, despite the fact that IOD wearers report superiority in their masticatory performance and ability to chew a greater variety foods [127,128,135]?

The fact that this study revealed similar dietary intake between the groups suggests that either the same foods were eaten, but prepared differently, or that different foods with similar nutritional profiles were consumed. We believe that the reported differences in the way in which patients in both groups prepare their foods [62] helped to produce similar dietary intake effects, e.g. a person who bites an apple will take in the same nutrients as someone who uses a knife to cut the apple into pieces or drinks pure apple juice. Furthermore, our study participants were healthy, independently living elders who demonstrated a good nutritional state at baseline. They also had above average educational levels and incomes. Thus, they were most probably always health conscious and capable of choosing and preparing foods appropriately to compensate for difficulties in

chewing. Therefore, the chance of gaining nutritional benefit in this population may be limited.

Second, what are the possible causes of the few significant differences found by the regression model for sex adjusting for treatment and baseline values and for baseline values adjusting for treatment received and sex? Those significant differences by sex are expected because males and females do differ in nutrition and calories intake [136]. In addition, some significant differences between baseline and post treatment values are also expected because it is possible that, irrespective of treatment received, both groups modified their diets from baseline due to receiving new prostheses.

Third, what are the implications of these similarities and what could have been done to improve the chance of finding any potential differences? We believe that changing dietary habits, including the types of foods consumed, may be a multifactorial adaptation process that likely takes much longer than a year to produce a measurable effect [137]. Furthermore, dietary counseling can improve fruit and vegetable intake in an edentulous individual [138]. Our study participants were not given specific individual dietary counseling before or during the study and, consequently, could have needed more time to adapt their eating habits to the new treatment. Thus, an RCT in which participants are followed for a longer period of time and in which they are given specific individual dietary counseling

might maximize the possibility of dietary improvement. [114]

In conclusion, we believe that, although there is much evidence supporting the adoption of two-implant mandibular overdenture (IOD) treatment as the standard of care for edentate patients, this evidence does not include an improvement in dietary intake at one year for healthy independent edentate elders who are not given specific dietary counseling.

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Table 1. Between-group – Baseline and Twelve Months Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients for IOD and CD Groups.

		Baseline Results			
Variables	Group	Mean (STD.)*	Median (Q1, Q3)†	95% CI‡	P-value§
Fiber (TDF) (g)	IOD	16.3 (7.7)	14.7 (11.6, 18.7)		
	CD	15.7 (7.1)	14.9 (10.9, 19.0)	(-1.3, 1.8)	0.81
Energy (KCal)	IOD	1540.2 (541.7)	1432.7 (1150.7, 1909.3)		
	CD	1557.4 (554.2)	1478 (1147.5, 1877.4)	(-160.0, 114.0)	0.72
Macronutrients:					
PROT. (g)	IOD	67.7 (22.3)	66.1 (50.4, 79.4)		
	CD	67.1 (24.8)	62.8 (52.7, 79.0)	(-4.2, 7.5)	0.55
FAT. (g)	IOD	56.8 (23.6)	51.6 (38.9, 70.1)		
	CD	59.3 (27.4)	53.3 (41.4, 72.3)	(-8.0, 3.9)	0.57
CARB. (g)	IOD	189.2 (80.5)	166.7 (135.2, 235.0)		
	CD	185.6 (69.2)	174.6 (136.3, 233.8)	(-20.4, 16.4)	0.84
Micronutrients:					
VIT A (ɲg)	IOD	675.8 (922.6)	533.3 (342.3, 733.3)		
	CD	830.5 (1016.6)	562.2 (371.3, 860.1)	(-118.3, 38.7)	0.38
VIT. D (ɲg)	IOD	4.7 (4.1)	3.1 (2.2, 6.1)		
	CD	3.8 (3.2)	3.1 (1.9, 4.7)	(-0.1, 1.0)	0.13
VIT. C (mg)	IOD	108.5 (75.6)	90.5 (58.2, 141.2)		
	CD	100.6 (64.8)	86.1 (53.9, 130.8)	(-10.6, 19.9)	0.53
THIA. (mg)	IOD	1.4 (0.7)	1.3 (0.9, 1.8)		
	CD	1.4 (0.5)	1.3 (1.1, 1.8)	(-0.2, 0.1)	0.69
RIBO. (mg)	IOD	2.0 (1.6)	1.7 (1.4, 2.2)		
	CD	1.8 (0.7)	1.7 (1.4, 2.2)	(-0.1, 0.2)	0.69
Niacin (NEs)	IOD	31.2 (10.5)	30.5 (24.1, 38.2)		
	CD	31.4 (12.0)	28.3 (23.8, 37.6)	(-2.3, 3.1)	0.76
VIT. B6 (mg)	IOD	1.5 (0.6)	1.4 (1.1, 1.8)		
	CD	1.5 (0.6)	1.4 (1.1, 1.8)	(-0.1, 0.2)	0.53
VIT. B12 (ɲg)	IOD	3.9 (2.9)	3.3 (2.3, 4.7)		
	CD	5.4 (7.8)	2.8 (2.0, 5.1)	(-0.3, 0.6)	0.44
DFE (Folate) (ɲg)	IOD	355.4 (148.5)	308.3 (262.0, 442.7)		
	CD	349.5 (135.2)	326.7 (243.8, 433.1)	(-33.3, 36.0)	0.88

* Mean (Standard Deviation)

† Median and quartiles (25th [Q1] and 75th [Q3])

‡ 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method

§ P-value is obtained from Wilcoxon rank-sum test

Table 1. (Continued) Between-group – Baseline and Twelve Months Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients for IOD and CD Groups.

		Twelve Months Results			
Variables	Group	Mean (STD.)*	Median (Q1, Q3)†	95% CI‡	P-value§
Fiber (TDF) (g)	IOD	15.9 (7.3)	14.5 (11.1, 19.0)		
	CD	16.8 (7.7)	15.4 (11.5, 19.9)	(-2.4, 1.0)	0.36
Energy (KCal)	IOD	1474.4 (431.7)	1469.7 (1201.3, 1633.0)		
	CD	1505.7 (482.0)	1403.0 (1193.7, 1741.1)	(-123.3, 108.7)	0.96
Macronutrients:					
PROT. (g)	IOD	64.7 (22.5)	61.8 (49.2, 77.6)		
	CD	65.0 (22.7)	61.4 (49.7, 78.1)	(-5.7, 5.2)	0.94
FAT. (g)	IOD	56.0 (20.0)	54.4 (41.1, 67.5)		
	CD	55.3 (19.5)	53.0 (41.8, 66.3)	(-4.2, 6.2)	0.64
CARB. (g)	IOD	177.1 (59.6)	173.9 (133.6, 198.4)		
	CD	187.1 (83.5)	174.6 (141.4, 213.0)	(-18.1, 10.0)	0.64
Micronutrients:					
VIT A (ɲg)	IOD	661.1 (672.7)	525.7 (385.7, 769.0)		
	CD	713.4 (717.3)	572.7 (357.9, 797.4)	(-96.7, 52.7)	0.63
VIT. D (ɲg)	IOD	4.1 (3.6)	3.3 (2.0, 5.0)		
	CD	4.2 (4.9)	3.1 (1.8, 5.0)	(-0.3, 0.7)	0.41
VIT. C (mg)	IOD	98.5 (71.7)	91.2 (47.9, 131.0)		
	CD	104.3 (65.3)	89.0 (61.0, 143.1)	(-22.8, 8.9)	0.36
THIA. (mg)	IOD	1.5 (0.7)	1.3 (1.0, 1.8)		
	CD	1.4 (0.6)	1.3 (1.1, 1.6)	(-0.1, 0.1)	0.98
RIBO. (mg)	IOD	1.8 (0.6)	1.7 (1.4, 2.1)		
	CD	1.9 (1.7)	1.7 (1.4, 2.0)	(-0.1, 0.2)	0.68
Niacin (NEs)	IOD	30.8 (11.8)	28.5 (23.6, 36.8)		
	CD	30.2 (11.1)	28.6 (23.5, 35.3)	(-2.3, 2.8)	0.85
VIT. B6 (mg)	IOD	1.6 (1.1)	1.4 (1.1, 1.7)		
	CD	1.5 (0.6)	1.4 (1.2, 1.7)	(-0.2, 0.1)	0.47
VIT. B12 (ɲg)	IOD	4.4 (5.6)	2.8 (2.0, 4.1)		
	CD	3.8 (3.4)	3.1 (2.2, 4.3)	(-0.5, 0.3)	0.66
DFE (Folate) (ɲg)	IOD	362.9 (193.3)	340.0 (252.7, 419.0)		
	CD	340.4 (116.8)	315.2 (255.7, 413.7)	(-21.7, 42.3)	0.56

* Mean (Standard Deviation)

† Median and quartiles (25th [Q1] and 75th [Q3])

‡ 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method

§ P-value is obtained from Wilcoxon rank-sum test

Table 2. Between-group – Twelve months Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients after Stratification by Sex for IOD and CD Groups.

	Male Results			
	CD Group	IOD Group		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	16.0 (12.5, 21.4)	16.1 (11.5, 21.1)	(-3.2, 2.1)	0.63
Energy (KCal)	1452.3 (1220.8, 1987.7)	1527.7 (1339.0, 1828.3)	(-152.0, 223.0)	0.58
Macronutrients				
PROT. (g)	64.9 (53.1, 81.3)	66.6 (53.2, 89.9)	(-5.8, 11.8)	0.57
FAT. (g)	58.2 (42.2, 74.4)	59.0 (47.8, 72.0)	(-7.3, 9.7)	0.78
CARB. (g)	186.0 (152.0, 222.9)	188.3 (158.7, 226.0)	(-21.8, 26.4)	0.82
Micronutrients				
VIT A (ฑg)	606.0 (359.5, 875.7)	574.0 (388.7, 814.0)	(-131.5, 116.0)	0.97
VIT. D (ฑg)	3.3 (2.0, 5.3)	4.0 (2.5, 5.8)	(-0.4, 1.5)	0.27
VIT. C (mg)	83.9 (62.1, 137.6)	88.0 (42.0, 131.0)	(-26.0, 17.8)	0.64
THIA. (mg)	1.4 (1.1, 1.7)	1.5 (1.1, 2.3)	(-0.1, 0.4)	0.22
RIBO. (mg)	1.8 (1.5, 2.1)	1.9 (1.6, 2.3)	(-0.1, 0.3)	0.17
Niacin (NEs)	30.4 (24.7, 37.2)	31.0 (25.1, 41.4)	(-2.8, 5.1)	0.61
VIT. B6 (mg)	1.4 (1.2, 1.8)	1.4 (1.1, 1.9)	(-0.2, 0.2)	0.93
VIT. B12 (ฑg)	3.4 (2.3, 4.7)	3.5 (2.3, 5.3)	(-0.7, 0.7)	0.94
DFE (Folate) (ฑg)	337.3 (283.3, 471.7)	378.7 (290.7, 457.7)	(-38.3, 70.3)	0.64

* Median and quartiles (25th [Q1] and 75th [Q3])
† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
‡ P-value is obtained from Wilcoxon rank-sum test

Table 2. (Continued) Between-group – Twelve months Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients after Stratification by Sex for IOD and CD Groups.

	Female Results			
	CD Group	IOD Group		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	14.7 (10.3, 19.7)	13.9 (10.3, 17.9)	(-2.9, 1.4)	0.45
Energy (KCal)	1357.0 (1105.8, 1648.7)	1335.7 (1080.3, 1581.6)	(-173.7, 104.3)	0.61
Macronutrients				
PROT. (g)	57.5 (47.4, 74.9)	59.2 (45.4, 68.0)	(-8.9, 5.1)	0.65
FAT. (g)	51.4 (39.5, 58.3)	50.4 (37.9, 63.2)	(-5.7, 7.2)	0.79
CARB. (g)	166.7 (124.3, 188.9)	161.3 (125.0, 182.4)	(-25.6, 9.0)	0.41
Micronutrients				
VIT A (ɲg)	542.5 (357.5, 709.0)	434.2 (369.8, 704.5)	(-138.3, 52.3)	0.42
VIT. D (ɲg)	2.8 (1.7, 4.8)	3.1 (1.9, 4.7)	(-0.6, 0.7)	0.93
VIT. C (mg)	107.3 (59.0, 148.1)	93.1 (49.7, 134.0)	(-33.1, 12.6)	0.37
THIA. (mg)	1.3 (1.1, 1.5)	1.1 (0.9, 1.6)	(-0.2, 0.1)	0.32
RIBO. (mg)	1.5 (1.3, 2.0)	1.6 (1.4, 1.8)	(-0.2, 0.1)	0.81
Niacin (NEs)	27.2 (21.9, 33.8)	27.3 (20.5, 33.6)	(-3.6, 3.0)	0.95
VIT. B6 (mg)	1.4 (1.1, 1.7)	1.3 (1.0, 1.6)	(-0.2, 0.1)	0.30
VIT. B12 (ɲg)	2.7 (2.0, 3.9)	2.7 (1.8, 3.4)	(-0.7, 0.3)	0.59
DFE (Folate) (ɲg)	309.0 (242.3, 379.2)	316.7 (249.0, 396.6)	(-30.0, 44.3)	0.71

* Median and quartiles (25th [Q1] and 75th [Q3])

† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method

‡ P-value is obtained from Wilcoxon rank-sum test

Table 3. The Association between nutrients and treatment adjusted for baseline values, sex.*

Variable	B †	95% CI
Total Dietary Fiber (TDF)		
IOD (vs. CD)	1.0	-0.57, 2.57
Female (vs. male)	-0.2	-1.83, 1.43
Baseline intake, g	0.4	0.29, 0.51
Energy		
IOD (vs. CD)	-46.2	-160.26, 67.8
Female (vs. male)	-132.4	-258.6, -6.2**
Baseline intake, KCal.	0.11	0.01, 0.22**
PROT.		
IOD (vs. CD)	-0.80	-9.0, 7.4
Female (vs. male)	-4.8	-13.6, 3.9
Baseline intake, g	0.21	0.01, 0.39**
FAT		
IOD (vs. CD)	-1.2	-7.0, 4.5
Female (vs. male)	-6.3	-12.4, -0.22
Baseline intake, g	0.08	-0.4, 0.2
CARB.		
IOD (vs. CD)	-0.16	-11.2, 10.9
Female (vs. male)	-11.9	-24.1, 2.9
Baseline intake, g	0.11	0.02, 0.19
VIT A		
IOD (vs. CD)	93.0	-27.3, 213.3
Female (vs. male)	-100.71	-221.3, 19.9
Baseline intake, **µg**	0.03	-0.02, 0.08
VIT. D		
IOD (vs. CD)	-0.2	-0.85, 0.47
Female (vs. male)	-0.4	-1.07, 0.27
Baseline intake, **µg**	0.2	-0.11, 0.3
VIT. C		
IOD (vs. CD)	10.67	-12.02, 33.4
Female (vs. male)	11.9	-10.7, 34.6
Baseline intake, mg	0.3	0.14, 0.46
THIA.		
IOD (vs. CD)	-0.05	-0.22, 0.10
Female (vs. male)	-0.22	-0.41, -0.05**
Baseline intake, mg	1.6	1.13, 2.06**
RIBO.		
IOD (vs. CD)	0.004	-0.03, 0.2
Female (vs. male)	1.0	0.30, 1.7**
Baseline intake, mg	0.003	0.002, 0.07**
Niacin		
IOD (vs. CD)	0.22	-4.3, 3.92
Female (vs. male)	-2.22	-6.8, 2.3
Baseline intake, **NEs**	0.11	-0.09, 0.31
VIT. B6		
IOD (vs. CD)	-0.001	-0.91, 0.92
Female (vs. male)	-0.006	-0.94, 0.96
Baseline intake, mg	0.05	-0.24, 1.25
VIT. B12		
IOD (vs. CD)	-0.06	-1.83, 0.62
Female (vs. male)	0.03	-1.52, 0.94
Baseline intake, **µg**	0.05	-0.06, 0.15
DFE (Folate)		
IOD (vs. CD)	-14.64	-50.6, 21.3
Female (vs. male)	-45.24	83.0, 7.5**
Baseline intake, **µg**	0.23	0.10, 0.36**

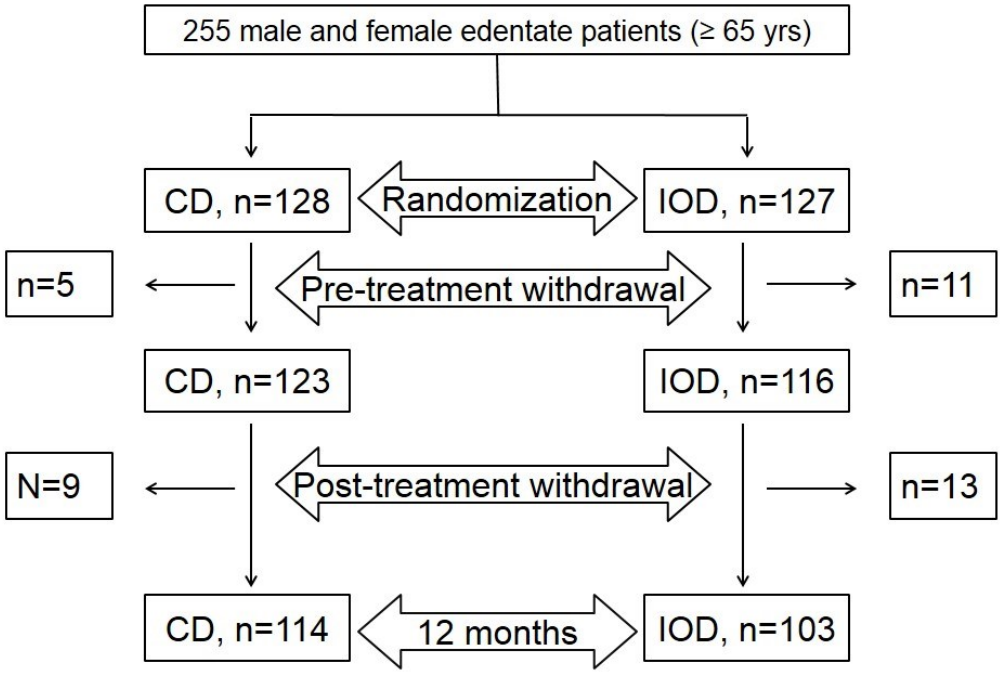
* Analysis was based on quantile regression.

† Unstandardized regression coefficient

** P<0.05

Figure Caption

Figure 1. Flow chart of participants' enrolment in the study (up to one year post-treatment)



CHAPTER 4

Summary of Findings Not Reported In the Research Manuscript

The objective of this study was to determine whether or not two treatment groups, wearing either a new mandibular CD or IOD, differed in their dietary intake 12 months post-treatment. We found no significant differences between the two groups at the 12 month assessment. However, we wished to determine whether the average daily dietary intake within each group changed from baseline to 12 months. We have investigated that question in this section at the level of the group, then after stratification by sex.

4.1 Within-group Comparisons – Baseline & Twelve-month Results

No statistically significant difference was found within-group between baseline and 12 months for daily intakes of TDF, energy, macro- and micronutrients in both the CD ($P \geq 0.39$) and the IOD group ($P \geq 0.17$). (Table 4.1)

4.2 Within-group (CD) – Baseline & Twelve-month Results/ Stratified by Sex

Table 4.2 shows the within-group comparison of male and female baseline and 12 month daily intakes of TDF, energy, macro- and micronutrients for the CD group. Within the CD-female subgroup, a non-significant difference was found for all comparators ($P \geq 0.08$), except for Vitamin B6, for which the baseline and twelve-

month values were statistically different (P = 0.02) as the consumption of Vitamin B6 increased 12 months after treatment. The CD-male subgroup, baseline and twelve-month values were not statistically different for the intake of TDF, fat, carbohydrate, vitamin A, vitamin D, vitamin C, riboflavin, vitamin B6, vitamin B12 and folate (P ≥0.07). However, a statistically significant difference was found between the CD-male baseline and 12-month values for the intake of energy (P = 0.03), protein (P = 0.04), thiamin (P = 0.02) and niacin (P = 0.03) as the consumption of energy and those three micronutrients decreased 12 months post-treatment.

4.3 Within-group (IOD) – Baseline & Twelve-month Results/ Stratified by Sex

Table 4.3 shows the within-group comparison of male and female baseline and twelve-month daily intakes of TDF, energy, macro- and micronutrients for the IOD group. No significant differences were found for any of the comparators for both the IOD-male (P ≥0.18) and the IOD-female (P ≥0.14) subgroups.

Table 4.1. Within-group comparison for both CD & IOD – Baseline and Twelve-month Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients for IOD and CD Groups.

		CD Results			
Variables	Time	Mean (STD.)*	Median (Q1, Q3)†	95% CI‡	P-value§
Fiber (TDF) (g)	Baseline	15.7 (7.1)	14.9 (10.9, 19.0)		
	12 months	16.8 (7.7)	15.4 (11.5, 19.9)	(-2.4, 0.8)	0.39
Energy (KCal)	Baseline	1557.4 (554.2)	1478 (1147.5, 1877.4)		
	12 months	1505.7 (482.0)	1403.0 (1193.7, 1741.1)	(-86.7, 170.7)	0.51
Macronutrients:					
PROT. (g)	Baseline	67.1 (24.8)	62.8 (52.7, 79.0)		
	12 months	65.0 (22.7)	61.4 (49.7, 78.1)	(-3.9, 6.7)	0.56
FAT. (g)	Baseline	59.3 (27.4)	53.3 (41.4, 72.3)		
	12 months	55.3 (19.5)	53.0 (41.8, 66.3)	(-3.6, 7.7)	0.46
CARB. (g)	Baseline	185.6 (69.2)	174.6 (136.3, 233.8)		
	12 months	187.1 (83.5)	174.6 (141.4, 213.0)	(-13.9, 19.2)	0.81
Micronutrients:					
VIT A (ɱg)	Baseline	830.5 (1016.6)	562.2 (371.3, 860.1)		
	12 months	713.4 (717.3)	572.7 (357.9, 797.4)	(-78.7, 83.3)	0.96
VIT. D (ɱg)	Baseline	3.8 (3.2)	3.1 (1.9, 4.7)		
	12 months	4.2 (4.9)	3.1 (1.8, 5.0)	(-0.6, 0.4)	0.71
VIT. C (mg)	Baseline	100.6 (64.8)	86.1 (53.9, 130.8)		
	12 months	104.3 (65.3)	89.0 (61.0, 143.1)	(-19.7, 10.1)	0.51
THIA. (mg)	Baseline	1.4 (0.5)	1.3 (1.1, 1.8)		
	12 months	1.4 (0.6)	1.3 (1.1, 1.6)	(-0.1, 0.1)	0.70
RIBO. (mg)	Baseline	1.8 (0.7)	1.7 (1.4, 2.2)		
	12 months	1.9 (1.7)	1.7 (1.4, 2.0)	(-0.1, 0.2)	0.86
Niacin (NEs)	Baseline	31.4 (12.0)	28.3 (23.8, 37.6)		
	12 months	30.2 (11.1)	28.6 (23.5, 35.3)	(-1.7, 3.2)	0.57
VIT. B6 (mg)	Baseline	1.5 (0.6)	1.4 (1.1, 1.8)		
	12 months	1.5 (0.6)	1.4 (1.2, 1.7)	(-0.2, 0.1)	0.38
VIT. B12 (ɱg)	Baseline	5.4 (7.8)	2.8 (2.0, 5.1)		
	12 months	3.8 (3.4)	3.1 (2.2, 4.3)	(-0.4, 0.4)	0.93
DFE (Folate) (ɱg)	Baseline	349.5 (135.2)	326.7 (243.8, 433.1)		
	12 months	340.4 (116.8)	315.2 (255.7, 413.7)	(-29.7, 34.7)	0.87

* Mean (Standard Deviation)
† Median and quartiles (25th [Q1] and 75th [Q3])
‡ 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
§ P-value is obtained from Wilcoxon rank-sum test

Table 4.1. (Continued) Within-group comparison for both CD & IOD – Baseline and Twelve-month Average Mean and Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients for IOD and CD Groups.

		IOD Results			
Variables	Time	Mean (STD.)*	Median (Q1, Q3)†	95% CI‡	P-value§
Fiber (TDF) (g)	Baseline	16.3 (7.7)	14.7 (11.6, 18.7)		
	12 months	15.9 (7.3)	14.5 (11.1, 19.0)	(-1.8, 1.4)	0.82
Energy (KCal)	Baseline	1540.2 (541.7)	1432.7 (1150.7, 1909.3)		
	12 months	1474.4 (431.7)	1469.7 (1201.3, 1633.0)	(-161.3, 98.7)	0.68
Macronutrients:					
PROT. (g)	Baseline	67.7 (22.3)	66.1 (50.4, 79.4)		
	12 months	64.7 (22.5)	61.8 (49.2, 77.6)	(-9.3, 2.7)	0.28
FAT. (g)	Baseline	56.8 (23.6)	51.6 (38.9, 70.1)		
	12 months	56.0 (20.0)	54.4 (41.1, 67.5)	(-4.7, 6.7)	0.73
CARB. (g)	Baseline	189.2 (80.5)	166.7 (135.2, 235.0)		
	12 months	177.1 (59.6)	173.9 (133.6, 198.4)	(-21.1, 13.8)	0.72
Micronutrients:					
VIT A (µg)	Baseline	675.8 (922.6)	533.3 (342.3, 733.3)		
	12 months	661.1 (672.7)	525.7 (385.7, 769.0)	(-57.7, 85.0)	0.67
VIT. D (µg)	Baseline	4.7 (4.1)	3.1 (2.2, 6.1)		
	12 months	4.1 (3.6)	3.3 (2.0, 5.0)	(-0.7, 0.5)	0.66
VIT. C (mg)	Baseline	108.5 (75.6)	90.5 (58.2, 141.2)		
	12 months	98.5 (71.7)	91.2 (47.9, 131.0)	(-23.3, 9.2)	0.41
THIA. (mg)	Baseline	1.4 (0.7)	1.3 (0.9, 1.8)		
	12 months	1.5 (0.7)	1.3 (1.0, 1.8)	(-0.1, 0.2)	0.78
RIBO. (mg)	Baseline	2.0 (1.6)	1.7 (1.4, 2.2)		
	12 months	1.8 (0.6)	1.7 (1.4, 2.1)	(-0.2, 0.1)	0.85
Niacin (NEs)	Baseline	31.2 (10.5)	30.5 (24.1, 38.2)		
	12 months	30.8 (11.8)	28.5 (23.6, 36.8)	(-3.7, 1.9)	0.51
VIT. B6 (mg)	Baseline	1.5 (0.6)	1.4 (1.1, 1.8)		
	12 months	1.6 (1.1)	1.4 (1.1, 1.7)	(-0.2, 0.1)	0.61
VIT. B12 (µg)	Baseline	3.9 (2.9)	3.3 (2.3, 4.7)		
	12 months	4.4 (5.6)	2.8 (2.0, 4.1)	(-0.7, 0.2)	0.17
DFE (Folate) (µg)	Baseline	355.4 (148.5)	308.3 (262.0, 442.7)		
	12 months	362.9 (193.3)	340.0 (252.7, 419.0)	(-30.7, 40.0)	0.77

* Mean (Standard Deviation)
† Median and quartiles (25th [Q1] and 75th [Q3])
‡ 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
§ P-value is obtained from Wilcoxon rank-sum test

Table 4.2. Within-group (CD) – Baseline & Twelve-month Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients After Stratification by Sex for CD Group.

	Male Results			
	Baseline	Twelve Months		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	16.3 (13.0, 20.1)	16.0 (12.5, 21.4)	(-2.1, 2.4)	0.87
Energy (KCal)	1676.3 (1460.2, 2148.3)	1452.3 (1220.8, 1987.7)	(36.3, 408.0)	0.03**
Macronutrients				
PROT. (g)	74.4 (61.8, 90.9)	64.9 (53.1, 81.3)	(0.2, 16.3)	0.04**
FAT. (g)	66.5 (47.6, 84.2)	58.2 (42.2, 74.4)	(-1.6, 17.3)	0.09
CARB. (g)	210.1 (170.8, 260.5)	186.0 (152.0, 222.9)	(-1.2, 50.7)	0.07
Micronutrients				
VIT A (ﾊg)	577.0 (409.8, 933.3)	606.0 (359.5, 875.7)	(-104.7, 158.3)	0.71
VIT. D (ﾊg)	3.6 (2.4, 5.0)	3.3 (2.0, 5.3)	(-0.6, 1.0)	0.50
VIT. C (mg)	96.4 (62.6, 150.0)	83.9 (62.1, 137.6)	(-14.2, 29.9)	0.46
THIA. (mg)	1.6 (1.3, 1.9)	1.4 (1.1, 1.7)	(0.03, 0.4)	0.02**
RIBO. (mg)	1.9 (1.7, 2.4)	1.8 (1.5, 2.1)	(-0.04, 0.4)	0.13
Niacin (NEs)	36.1 (27.9, 43.1)	30.4 (24.7, 37.2)	(0.4, 8.2)	0.03**
VIT. B6 (mg)	1.6 (1.2, 2.0)	1.4 (1.2, 1.8)	(-0.1, 0.3)	0.28
VIT. B12 (ﾊg)	3.5 (2.4, 5.6)	3.4 (2.3, 4.7)	(-0.4, 1.0)	0.45
DFE (Folate) (ﾊg)	404.7 (292.2, 487.5)	337.3 (283.3, 471.7)	(-25.0, 87.0)	0.28

* Median and quartiles (25th [Q1] and 75th [Q3])
† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
‡ P-value is obtained from Wilcoxon rank-sum test
** P<0.05

Table 4.2. (Continued) Within-group (CD) – Baseline & Twelve-month Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients After Stratification by Sex for CD Group.

	Female Results			
	Baseline	Twelve Months		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	12.6 (10.1, 18.2)	14.7 (10.3, 19.7)	(-3.8, 0.6)	0.16
Energy (KCal)	1258.0 (1040.0, 1581.2)	1357.0 (1105.8, 1648.7)	(-229.0, 55.7)	0.20
Macronutrients				
PROT. (g)	56.4 (44.7, 66.3)	57.5 (47.4, 74.9)	(-10.1, 3.5)	0.38
FAT. (g)	48.9 (36.8, 60.0)	51.4 (39.5, 58.3)	(-7.7, 4.1)	0.47
CARB. (g)	150.6 (110.8, 188.0)	166.7 (124.3, 188.9)	(-33.4, 3.2)	0.11
Micronutrients				
VIT A (ﾊg)	532.3 (353.3, 736.7)	542.5 (357.5, 709.0)	(-123.0, 89.7)	0.80
VIT. D (ﾊg)	2.5 (1.2, 4.3)	2.8 (1.7, 4.8)	(-1.0, 0.3)	0.21
VIT. C (mg)	75.0 (51.3, 116.3)	107.3 (59.0, 148.1)	(-38.5, 5.8)	0.15
THIA. (mg)	1.1 (0.9, 1.5)	1.3 (1.1, 1.5)	(-0.1, 0.02)	0.08
RIBO. (mg)	1.5 (1.2, 1.8)	1.5 (1.3, 2.0)	(-0.3, 0.1)	0.28
Niacin (NEs)	25.9 (21.1, 30.1)	27.2 (21.9, 33.8)	(-4.6, 1.5)	0.30
VIT. B6 (mg)	1.2 (0.9, 1.6)	1.4 (1.1, 1.7)	(-0.3, -0.02)	0.02**
VIT. B12 (ﾊg)	2.5 (1.7, 3.6)	2.7 (2.0, 3.9)	(-0.7, 0.3)	0.39
DFE (Folate) (ﾊg)	270.3 (223.0, 361.3)	309.0 (242.3, 379.2)	(-53.0, 16.7)	0.28

* Median and quartiles (25th [Q1] and 75th [Q3])
† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
‡ P-value is obtained from Wilcoxon rank-sum test
** P<0.05

Table 4.3. Within-group (IOD) – Baseline & Twelve-month Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients after Stratification by Sex for IOD Group.

	Male Results			
	Baseline	Twelve Months		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	15.7 (11.6, 21.3)	16.1 (11.5, 21.1)	(-3.3, 2.6)	0.89
Energy (KCal)	1710.0 (1357.0, 2062.3)	1527.7 (1339.0, 1828.3)	(-154.7, 72.7)	0.18
Macronutrients				
PROT. (g)	73.8 (57.7, 87.8)	66.6 (53.2, 89.9)	(-14.6, 5.9)	0.38
FAT. (g)	60.0 (45.6, 82.8)	59.0 (47.8, 72.0)	(-12.9, 5.7)	0.49
CARB. (g)	207.8 (150.5, 281.7)	188.3 (158.7, 226.0)	(-54.2, 11.9)	0.21
Micronutrients				
VIT A (㎍)	582.0 (324.7, 772.3)	574.0 (388.7, 814.0)	(-67.3, 157.0)	0.45
VIT. D (㎍)	3.3 (2.1, 6.8)	4.0 (2.5, 5.8)	(-1.0, 1.2)	0.84
VIT. C (mg)	73.9 (47.5, 138.6)	88.0 (42.0, 131.0)	(-22.6, 25.0)	0.93
THIA. (mg)	2.1 (1.5, 2.6)	1.5 (1.1, 2.3)	(-0.3, 0.3)	0.89
RIBO. (mg)	1.9 (1.5, 2.3)	1.9 (1.6, 2.3)	(-0.2, 0.2)	0.94
Niacin (NEs)	34.4 (29.2, 41.3)	31.0 (25.1, 41.4)	(-6.7, 2.3)	0.29
VIT. B6 (mg)	1.7 (1.3, 2.1)	1.4 (1.1, 1.9)	(-0.3, 0.1)	0.43
VIT. B12 (㎍)	3.5 (2.6, 5.0)	3.5 (2.3, 5.3)	(-0.9, 0.7)	0.82
DFE (Folate) (㎍)	349.7 (273.3, 489.3)	378.7 (290.7, 457.7)	(-49.7, 66.3)	0.82

* Median and quartiles (25th [Q1] and 75th [Q3])
† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method
‡ P-value is obtained from Wilcoxon rank-sum test

Table 4.3. (Continued) Within-group (IOD) – Baseline & Twelve-month Median Daily Intakes of TDF, Energy, Macronutrients and Nine Micronutrients after Stratification by Sex for IOD Group.

	Female Results			
	Baseline	Twelve Months		
Variables	Median (Q1, Q3) *	Median (Q1, Q3) *	95% CI†	P-value‡
Fiber (TDF) (g)	14.2 (11.7, 17.3)	13.9 (10.3, 17.9)	(-2.0, 1.7)	0.82
Energy (KCal)	1271.7 (1024.8, 1534.3)	1335.7 (1080.3, 1581.6)	(-96.0, 192.7)	0.52
Macronutrients				
PROT. (g)	58.2 (47.3, 71.3)	59.2 (45.4, 68.0)	(-8.4, 5.0)	0.68
FAT. (g)	47.8 (37.7, 59.7)	50.4 (37.9, 63.2)	(-3.2, 10.5)	0.31
CARB. (g)	147.7 (120.6, 184.6)	161.3 (125.0, 182.4)	(-14.2, 21.6)	0.61
Micronutrients				
VIT A (ﾊg)	502.5 (345.6, 718.6)	434.2 (369.8, 704.5)	(-108.7, 81.0)	0.99
VIT. D (ﾊg)	3.0 (2.3, 5.0)	3.1 (1.9, 4.7)	(-1.0, 0.3)	0.31
VIT. C (mg)	105.6 (64.0, 145.3)	93.1 (49.7, 134.0)	(-37.2, 7.9)	0.19
THIA. (mg)	1.1 (0.9, 1.5)	1.1 (0.9, 1.6)	(-0.1, 0.2)	0.45
RIBO. (mg)	1.5 (1.2, 2.0)	1.6 (1.4, 1.8)	(-0.2, 0.2)	0.83
Niacin (NEs)	25.7 (20.6, 31.9)	27.3 (20.5, 33.6)	(-2.9, 3.7)	0.79
VIT. B6 (mg)	1.3 (1.1, 1.6)	1.3 (1.0, 1.6)	(-0.1, 0.2)	0.90
VIT. B12 (ﾊg)	3.0 (2.0, 4.3)	2.7 (1.8, 3.4)	(-0.9, 0.1)	0.14
DFE (Folate) (ﾊg)	294.7 (221.7, 403.7)	316.7 (249.0, 396.6)	(-41.0, 48.0)	0.90

* Median and quartiles (25th [Q1] and 75th [Q3])

† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair using Wilcoxon method

‡ P-value is obtained from Wilcoxon rank-sum test

CHAPTER 5

DISCUSSION

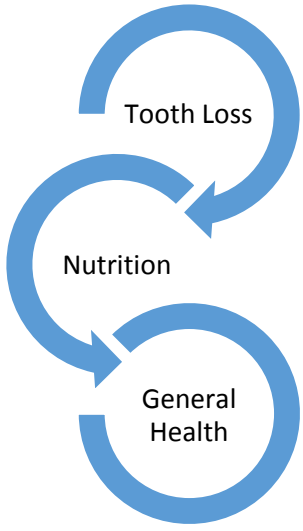
5.1 Findings from the Literature Review

There is ample evidence linking tooth loss with a subsequent increased risk of a host of systemic diseases. This could have serious consequences, ranging from any stage of disability to premature death. This link heightened researchers' interest in studying the potential effects of different forms of oral rehabilitation among specific age groups. However, because they are more likely to be affected by tooth loss, the elderly have been the focus of most research activity on this topic.

5.1.1 Old Age and Nutrition:

There is substantial evidence that the elderly develop special nutritional requirements either as a result of tooth loss or simply as a consequence of changes in physiology, psychology, metabolism and function that accompany the aging process [64,65,69]. Regardless of the aetiology, elders who have obvious nutritional problems , are likely to suffer more disability and are at greater risk of premature death than elders without nutritional problems [51]. Yet, there was no agreement between those few studies that looked at the complex interrelationship between nutrition and old age as whether the aging process

itself, regardless of dentition status, leads to poor nutrition [64-66] or whether poor nutrition is a consequence of losing teeth and the consequent loss of masticatory efficiency [67-72]. It is worth mentioning that those studies used cross-sectional designs, likely because it would be impossible to carry out an RCT to test this question. Nevertheless, when edentulism is involved in the old age – nutrition relationship, common agreement is that general health of the elderly is affected by tooth loss through its effect on diet. Nutrition is an important factor in many disease processes, and good food habits are an important component of healthy aging.



5.1.2 Dental Prostheses, Dentition Status and Nutrition:

There is accumulating evidence that loss of teeth is associated with poor nutrition, even when people wear dentures. Most of the evidence available agrees that edentate patients rehabilitated with conventional CDs have a

significantly poorer dietary intake than dentate or partially dentate subjects, and this makes them more vulnerable to the risk of malnutrition [73-79]. Again, some of those used small samples [74-76]. Because the former studies used non-randomized designs, most of them did not adjust for confounding elements that might have affected their findings, such as the environmental factors (geographic location), general health behaviours or socio-economic factors.

As previously stated, the evidence that the dentate or partially dentate enjoy better nutrition compared to the edentate, whether rehabilitated with a CD or not, is quite strong. However, this evidence was not conclusive when answering the question of whether providing the edentulous with new CDs or improving the technical quality of the existing CD improve nutrition. All studies agree that treatment with a CD provides some chewing function for edentate people. However, those studies that reported similar nutritional profiles of edentate people, whether wearing a CD or not, referred to the fact that prosthetic rehabilitation should be coupled with dietary advice in order to produce nutritional change. Yet, most of those studies were cross-sectional, pilot, exploratory or with a prospective comparative design. Many used small sample sizes and followed participants for short periods of time. Moreover, there was only one RCT to provide evidence that dietary counselling helps CD wearers to acquire better nutrition [95]. However, this RCT used a small sample size and followed participants for a short period. Again, this shows the need for RCTs that

use adequate sample sizes with sufficient follow-up periods to answer these nutritional questions.

5.1.3 IOD: The First Standard of Care – Consensus Reports:

There is an increasing agreement among scientists, experts and patients that treatment with IOD is a better choice and superior in many aspects to treatment with a CD. The recent review by Thomason et al. [99] summarized the advantages of IODs. The review also stated that there are still barriers for the delivery of this care for the benefit of edentulous patients.

5.1.4 CD, IOD and Nutrition:

There is clear evidence that simple treatment with dental implants to stabilize and support a mandibular conventional CD increases chewing efficiency. However, only two studies [102,103] stated that this alone has a positive effect on diet and nutrition. Although the findings from those two studies could be true, they seem not generalizable to other populations due to some characteristics of the studies' populations, known or unknown. Moreover, both studies were carried out in the same geographic location (Brazil). Thus, there might have been an environmental confounding effect that was not present in the other studies that found no effect. On the other hand, the results of eleven studies showed that treatment with IODs does not provide a significant nutritional benefit over treatment with CDs if not accompanied by individual dietary advice. Most of the

latter studies were RCTs, and one was a systematic review. Like the Brazilian studies, all of these used small sample sizes with short follow-up periods. The authors speculated that individual dietary advice might have been beneficial in producing positive nutritional change with IODs. This hypothesis was tested in only two studies [113,114]. Yet, both of those used small sample size with short follow-up periods. The use of small sample sizes reduces the statistical power of the study and thus reduces the study's ability to detect small to moderate treatment effects. Those low-powered studies are also more susceptible to random variation between study participants. This could either lead to false-negative or false-positive findings. It is also logical to believe that changes in nutrition or dietary intake among study participants require time to be measurable.

In conclusion, there is still a need for a well-powered RCT with a long follow-up period and in which well-validated methods are used to look at the potential nutritional benefits of IODs with and without tailored dietary advice. This might translate into recommendations for improving the dietary intake of millions of edentate elders that, in turn, could improve their general health and well-being and reduce their risks of greater morbidity and earlier mortality.

5.2 Findings of Results Not Reported In the Research Manuscript

Our analysis did not reveal statistically significant within-group differences for the

CD and IOD groups. The two groups had similar within-group baseline to 12-month post-treatment intakes of TDF, energy, macronutrients (proteins, fats and carbohydrates), as well as nine of the micronutrients. This was also true for the IOD within-group baseline to 12-month comparison when stratified by sex. However, this within-group comparison was not true for the CD group when stratified by sex. In the CD-female subgroup, there was a statistically significant increase from baseline to 12-month in median daily intakes of Vitamin B6. In the CD-male subgroup, there was a statistically significant decrease from baseline to 12-month in median daily intakes of energy, protein, thiamin and niacin. These within-group differences may have been due to an effect of multiple comparisons, rather than true differences. Our sample size, though adequate for between-group comparisons, might have not been suitable to compare 14 different items of two within-group comparisons stratified by sex. We recognise that we have limited power to address these potential subgroup effects, but consider them of interest, even though exploratory. Furthermore, as the within-group comparison was not one of the objectives of this study, our sample size may have been inadequate for this assessment, and multiple comparison adjustment was not considered. For those reasons the within-group results were not reported in the research manuscript.

5.3 More on Study Limitations

In addition to those reported in the research manuscript, there are a few important limitations of our study:

1- Participants might have altered their usual dietary intake during the three-day monitoring period and/or fail to accurately report their food intake [139]. However, our study participants were trained on the reporting of food portions *a priori*, and repeated measures were taken to reduce the variability between subjects. Moreover, a dietitian interviewed each participant at baseline and trained them to use food models and portion sizes to enhance accuracy.

2- It is possible that the participants did not wear their prostheses as much or for as long as they had reported.

3- Among all available methods, there is general agreement that 24-hour dietary recall measurements are the most appropriate for studying population dietary intakes. However, the development of more accurate and applicable methods continues to be a critical area [140].

4- In this RCT, blinding of care providers or participants to type of treatment and outcome was not possible because of the nature of implant therapy and the use of patient based outcomes. However, those who entered and analyzed the data were blind to treatment allocation.

5.4 Generalizability of Findings

Though considered the most reliable for determining treatment effects, the external validity of randomized clinical trials is less than desired. Moreover, the study sample was self-selected. Thus, caution must be taken when generalizing the results of this study to the general population [61].

CHAPTER 6

CONCLUSIONS

It is believed that lack of teeth in the elderly is associated with poorer nutrition since their ability to eat with dental prostheses reduce their ability to chew harder, more nutritious foods. This leads to negative consequences on elders' general health, ranging from minor to serious.

Although there is much evidence supporting the adoption of two-implant mandibular overdenture (IOD) treatment as the standard of care for edentate patients, we found that this evidence does not include an improvement in dietary intake at one year for healthy, independent edentate elders who are given no specific dietary counseling.

Thus, tailored dietary advice combined with IOD treatment might prove to be necessary for healthy aging in edentate elders. However, this hypothesis requires further testing through well-powered RCTs that follow participants for long periods of time and control for possible confounding factors.

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Appendix: Summary of Included Studies

Table APP1: Articles that aimed to study or report the relationship between old age and nutrition

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Baker (2007)	N/A	An overview of some basic concept of the relation between old age and nutrition.	Overview	N/A	>65 yrs	N/A	Age
Ikebe (2005)	Osaka, Japan	To investigate the effect of ageing, occlusal support and TMJ condition and general health status on bite force in older adults.	Cross-sectional study	850 (F=390, M=460).	>60 yrs (mean= 66.6±4.3 yrs), independently-living people. 32 subjects (3.9% of participants) were edentulous.	Cross-sectional*	Dentition status
Kikutani (2013)	Eight cities in Japan	To determine the risk of malnutrition in some Japanese communities where the frail elderly receive public long-term care insurance.	Large-scale cross-sectional survey	716 (F=476, M=240)	Mean age of 83.2 ± 8.6 years/ living at home and receiving public long-term care insurance services	Cross-sectional*	Dentition and nutrition status
Jensen (2001)	USA	Review	Review on nutrition in the elderly	N/A	Elderly	N/A	Age
Lopez-Jornet (2013)	Murcia, Spain	To determine the risk of malnutrition in both institutionalized and non-institutionalized elderly people of the region of Murcia/ Spain	Cross-sectional study	465 (F=252, M=213)	≥65 yrs/ institutionalized and non-institutionalized individuals without serious health conditions.	Cross-sectional*	Institutionalization status, dentition status
Osterberg (1982)	Goteborg, Sweden	To relate dental state to dietary habits and, furthermore, to study the possible influence of some social factors on these relations	Cross-sectional investigation/ gerontological and geriatric population study in Goteborg, Sweden.	368 (F=188, M=180)	Age: 70 yrs.	Cross-sectional investigation.*	Dentition status

Table APP1 (Cont.): Articles that aimed to study or report the relationship between old age and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Pirlich (2001)	N/A	To review the prevalence and aetiology, the clinical impact and diagnosis of undrnutrition in the elderly and to discuss the possible therapeutic strategies in different clinical situations.	Review	N/A	Elderly	N/A	Age
Sheiham (2001)	UK	This part of the British National Diet and Nutrition Survey (NDNS) aimed to assess if there is a relationship between dental status in people 65 years and older and intake of certain nutrients and any link between dental status and blood-derived values of key nutrients.	Cross-sectional study	>690	≥65 yrs/ institutionalized and non-institutionalized individuals.	Cross-sectional*	Institutionalization status, dentition status
Wakai (2010)	Japan	To clarify the association of tooth loss with dietary intakes among dentists, for whom sufficient dental care is available.	Cross-sectional survey	20366 (F=1629, M=18737)	Mean age= 52.2 ± 12.1 years	Cross-sectional*	Dentition status

*Reflects a cross-sectional design irrespective of number of evaluations.

Table APP2: Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Allen (2005)	The University Dental School and Hospital, Cork, Ireland	To assess whether there was an association between diet, oral health related quality of life and social resources in a population of older edentulous adults, and, to assess the impact of provision of new complete replacement dentures	Prospective comparative clinical study	35 (F=23, M=12)	Independently living patients ranging in age from 52 to 77 years (median 65 years)	Baseline and 2 months post-treatment	Dentition status
Baxter (1981)	University of Pittsburgh, School of Dental Medicine - USA	**1-** To assess the nutritional quality of the diets of geriatric edentulous patients without complete dentures; **2-** To observe the effect of the insertion of acceptable complete denture prostheses on the diets of these patients.	Prospective comparative clinical study	23 (F=13, M=10)	Average = 65 yrs (range = 60 to 82). Participants in this study were patients seeking CD treatment. There was a wide variety of educational and economic backgrounds, but none of the patients were receiving public assistance.	Baseline and 1 to 3 months post-treatment	Dentition status
Bradbury (2006)	Dental-student clinics at Newcastle Dental Hospital - UK	To have a positive impact upon dietary behavior of patients receiving replacement complete dentures through a tailored dietary intervention.	RCT	58 (intervention group (n= 30); control group (n= 28))	Age: 65.4 yrs (SD=8.9) for the intervention group; 66.6 yrs (SD=6.7) for the control group. Participants were edentulous > 1 yr, community-dwelling, not type 1 insulin-diabetic, and with fruit and vegetable intakes < 500 g/day.	Pre-intervention and six weeks after receiving replacement dentures (Total period = 18 months)	Dietary intervention
Bradbury (2008)	Newcastle, UK	To determine if perceived chewing ability was predictive of fruit and vegetable intake; explore the predictive ability of knowledge, attitude, and self-identity; and compare intake between edentulous and dentate individuals.	Cross-sectional study	CD (n= 79: F=52, M=27)) and dentate persons (n= 52: F=27, M=25)	45-80 years/ edentulous > 1 yr and wearing full dentures, or having > 21 teeth and no denture; community-dwelling; not insulin-dependent diabetic; and if non-insulin-dependent diabetic or on a cholesterol-lowering diet, diagnosed > 6 mos.	Cross-sectional*	Dentition status

Table APP2 (Cont.): Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Budtz-Jørgensen (2000)	NA	To look at the possible advantages of rebuilding the dentition in older adults, primarily from the point of view of masticatory function and nutrition.	Literature review	NA	Geriatric	NA	Dentition status
Cousson (2012)	Clermont-Ferrand Dental Hospital - France	To determine whether elderly complete denture wearers have a higher risk of malnutrition than dentate controls.	Prospective comparative clinical study	97 (Study group (n= 50; F=21, M=29); control group (n= 47; F=31, M=16))	Age: (Study group= 70.1 ± 6.1, Control group= 70.1 ± 8.1). Independently living, retired, middle class subjects who were not on a strict diet.	Six months after treatment with a CD for the study group	Dentition status
De Marchi (2011)	The city of Carlos Barbosa - Brazil.	To evaluate whether oral status with emphasis in edentulism and complete dentures use was associated with the daily consumption of the recommended amounts of fruit and vegetables in south Brazilian community-dwelling older people.	Cross-sectional study, with a simple random sampling design.	282 (F=161, M=121)	A random sample of healthy and independently living south Brazilians. Only 26% of the examined sample had eight or more than eight teeth, and 43.7% were edentulous. Age: 60 - 89 yrs.	Cross-sectional*	Dentition status
Greksa (1995)	The general and prosthetic clinics of the Case Western Reserve University Dental School in Cleveland, Ohio - USA	To test the null hypothesis that there are no differences in dietary patterns or adequacy between edentulous patients and individuals with nearly complete dentitions.	Cross-sectional, comparative study.	72 (Study group n=34, F=18 and M=16; control group n=38, F=23 and M=15).	Age = 51 - 83 yrs (mean = 66.9 yrs). Study group subjects reported regularly wearing dentures, control group subjects had nearly complete dentitions (>24 teeth). No significant differences between samples in mean age, height, or weight or in the distribution of sex, ethnicity, marital status, occupation, or education.	Cross-sectional*	Dentition status

Table APP2 (Cont.): Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Gunji (2009)	Nihon University School of Dentistry at Matsudo - Japan	To investigate changes of diet and nutrient adequacy between complete denture wearers with their existing dentures and those with new dentures.	Matched-pairs clinical study	30 (F=13, M=17)	Age was: males, 74.3 ± 5.7 yrs and females, 72.9 ± 10.1 yrs; the mean body weight was: males, 55.7 ± 8.6 kg and females, 48.1 ± 8.6 kg; the mean BMI was: males, 21.7 ± 2.7 and females, 20.9 ± 3.1.	While the subjects wore their old dentures and 2 mos. following final denture adjustment.	Denture quality
Kagawa (2012)	Osaka, Japan	To investigate the association of masticatory ability and dental status with intake of fruits and vegetables after adjusting for other factors in independently living elderly Japanese subjects.	cross-sectional study	1535 (F=714, M=821).	>60 yrs (mean= 66.6±4.3 yrs), independently-living people: edentulous without replacement (15.9%), CD (14.8%), wearing removable partial dentures (40.4%), or had natural dentition (29.0%).	Cross-sectional*	Dentition status
Krall (1998)	Boston area - USA	To evaluate the intake of specific nutrients among partially or completely edentulous group of middle-aged and elderly men. The secondary aim was to examine the relationship of masticatory function to nutrient intake.	Prospective observational study	638 Men (Intact Dentition (114), Partial Dentures (123), Partially Comp. Dentition (101), Comp. Dentition (224), CDs (76))	Age (yrs): (Intact Dentition = 61 ± 8, Removable Partial Dentures =64 ± 8, Partially Compromised Dentition =60 ± 7, Compromised Dentition =62 ± 7, Full Dentures =64 ± 7) Participants were in good medical health at baseline	2 years	Dentition status
Lamy (1999)	Nursing homes in the Lie`ge area (Belgium)	To evaluate, in an institutionalized elderly population, whether poor oral status is a contributing factor in the development of undernutrition and is associated with less eating pleasure, more subjective eating difficulty and increased mashed food consumption.	Observational study	120 (F=91, M=29)	Mean = 81 ± 8 yrs (range = 65-96). All subjects suffered from one or more medical problems: Cardiovascular diseases (72.6% of the subjects), depression (23.3%), diabetes mellitus (16.7%) and gastrointestinal disorders (16.7%). All subjects had no cognitive impairment and no acute illness at the time of the study.	NA	Dentition status. Subjects were divided into 3 groups: edentulous without dentures or with one CD (22.5%); edentulous with two CDs (38.3%); dentate with or without partial dentures (39.2%).

Table APP2 (Cont.): Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Lin (2010)	Taiwan	To investigate the relationship between chewing ability and diet among elderly edentulous patients.	Observational study	103 (F=35, M=68)	Age > 65 yrs.	Cross-sectional*	Dentition status
Mishellany-Dutour (2008)	France	To assess the impact of age and dentition status on masticatory function	A three-arm case–control study	42 divided into three equal groups of six females and eight males each.	3 groups: G1 composed of young fully dentate subjects (35·6 ± 10·6 years); G2 of aged fully dentate subjects (68·8 ± 7·0 years) and G3 of aged CD wearers (68·1 ± 7·2 years). Subjects in group 3 had stable lower and upper CDs with no difficulty eating any kind of food. All subjects were had no masticatory disorders.	Cross-sectional*	Age, dentition status
Mojon (1999)	Geneva - Switzerland	To evaluate the relationship between oral health status and nutritional deficiency.	Cross-sectional clinical study.	324 (F=227, M= 97)	Mean = 85 yrs (STD 6.9). Institutionalized frail elderly. 49% were edentulous.	Cross-sectional*	Dentition status
Nagaranjani (2012)	DAPMRV Dental College and hospital, Bangalore, India.	To evaluate the effect of edentulousness and prosthetic treatment on the nutritional status of the individual.	Matched-pairs clinical study	94	50 to 80 yrs. Completely edentulous and in need of CDs for the first time. Patients with acute illness at the time of study or who had cognitive impairment were excluded.	16 months	Dentition status
Nowjack-Raymer (2003)	USA	To assess whether the intake of specific nutritious food items, dietary fiber, and levels of blood analyte differed between those who were edentulous and reported wearing complete upper and lower dentures and those who had all of their natural teeth.	Data taken from a cross-sectional survey that used a stratified, multi-staged, probability sample design.	Denture-wearers: 1,373 (F=56.7%), fully-dentate: 2,421 (F=51.2%).	Individuals aged 25 years and older who participated in the third US National Health and Nutrition Examination Survey (NHANES III), which was a nationally representative, cross-sectional survey.	6 years: 1988-1994	Dentition status

Table APP2 (Cont.): Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Papas (1998)	Boston area - USA	To study the interrelationship of oral health status, dietary intake, and education, and to define their relative impact on the middle aged and elderly.	NOHS that used volunteers as subjects. (observational study)	247 (F=142, M=105)	Mean age of 62.3. Dentate subjects (Volunteers) with at least 6 teeth.	16 months.	Dentition status
Papas (1998)	Boston area - USA	In Part I of this study, subjective statements of dentate status were among the many variables correlated with nutritional status. In Part II of the study, a subset of subjects received careful dental evaluations for more careful determination of whether dentate status and other oral parameters were predictive of nutrition variables.	Cross-sectional study.	Part I: 691 (F=449). Part II: 181	> 60 yrs old volunteers. Participants were excluded if they had an illnesses that could severely affect nutritional status.	Cross-sectional*	Dentition status
Prakash (2012)	D.A.P.M.R.V. Dental College and hospital, Bangalore, India	To evaluate the effect of edentulousness and prosthetic treatment on the nutritional status of the individual.	Prospective comparative clinical study	94 at baseline, 85 at 9 months after treatment.	Age: 50-80 yrs./ completely edentulous and in need of CDs for the first time, excluded if they had an acute illness at the time of study or had cognitive impairment	Baseline, 6 months and 9 months after CD treatment.	Dentition status
Sahyoun (2003)	USA	To examine dietary quality and nutrient intakes of participants wearing dentures with and without poor fit as determined by self-report (questionnaire) and by the assessment of trained licensed dentists.	Data taken from a cross-sectional survey that used a stratified, multi-staged, probability sample design.	4,820 (3,207 with at least 18 teeth; 1,613 wearing CDs (932 with Self-perceived good-fitting dentures; 681 with Self-perceived dentures needing refit))	Individuals aged 50 years and older who participated in the third US National Health and Nutrition Examination Survey (NHANES III), which was a nationally representative, cross-sectional survey.	6 years: 1988-1994	Dentition status & Denture Quality (Fitting)

Table APP2 (Cont.): Articles that described research on the complex interrelationships between dental prostheses, dentition status and nutrition.

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Shigli (2012)	Modern Dental College and Research Centre, Indore, India.	To assess the changes in the nutritional health of elderly adults before and 1 month after placement of dentures in completely edentulous individuals	Pilot study (prospective comparative clinical study)	35 (F=9, M=26)	60-84 yrs/ free from any systemic diseases which affect oral functions and had good residual ridge anatomy	1 month	Dentition Status
Shinkai (2002)	San Antonio, Texas, USA	To investigate the relationship of complete denture quality to masticatory performance, perceived ability to chew, and diet quality as measured by the Healthy Eating Index (HEI), an overall diet quality index.	Cross-sectional study.	54 (F=28, M=26)	45 to 77 years (mean 67.8 ± 7.2 years). All subjects who had both maxillary and mandibular complete dentures	Cross-sectional*	Denture quality
Wayler (1983)	USA	To investigate the impact of complete dentures and impaired natural dentition on masticatory performance and food choice in healthy aging men.	Cross-sectional study	814	3 groups: <40, 40-49, and >50 yrs. Participants were either completely edentulous, had either natural dentition only or natural dentition with a fixed replacement for missing teeth.	Cross-sectional*	Dentition status
Wostmann (2008)	Two nursing homes in Olfen and Ludinghausen, Germany	To identify the impact of denture improvement on the nutritional status as well as the oral health-related quality of life in geriatric patients.	Exploratory interventional clinical study	34 (F=21, M=13)	>60 yrs/ participants from 2 nursing homes, capable of feeding themselves and with dentures requiring repair or replacement. Patients addicted to medication, alcohol and/or drugs, suffering from malignant tumours, undergoing radiation therapy were excluded.	6 months	Denture quality

*Reflects a cross-sectional design irrespective of number of evaluations.

Table APP3: Articles that reported or followed up on two consensus statements advocating IODs as the first choice standard of care for edentulous patients

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Population Characteristics	Evaluation Period	Primary Classification
Das (2012)	USA	This survey was conducted to determine if, in 2011, U.S. academic prosthodontic experts' opinions were aligned with those in the two consensus statements, McGill (Canada 2002) and York (England 2009)	A Delphi method survey of academic prosthodontic experts' opinions	16	An expert panel of nationally representative academic prosthodontists.	N/A	N/A
Feine (2002)	Canada	This independent report was prepared to reflect the knowledge from published studies, expert opinions and patient experiences accumulated until 2002 in regards to adopting the IOD as the first choice of treatment for the edentulous mandible.	An independent consensus report.	N/A	Experts who work in areas relevant to the consensus question; available scientific knowledge on the topic; and personal experience of the patients/ participants.	N/A	N/A
Thomason (2009)	The Annual Conference of the BSSPD held in York, UK	This consensus statement was prepared as a useful guide for patients, clinicians and professional organizations and to stimulate wider debate. It was also hoped that it will inform discussions with providers of national healthcare and with independent funders.	A professional consensus statement	N/A	Presenters at the Annual Conference of the BSSPD (2009); council members of the BSSPD; and BSSPD members on the Society's website.	N/A	N/A
Thomason (2012)	N/A	To present the current evidence and rationale to support the McGill and York consensus statements	Literature review	N/A	Geriatric	N/A	Prosthetic treatment

Table APP4: Articles that reported on the relationship between IODs, CDs and nutrition

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Allen (2002)	Adult clinics at Newcastle Dental School and Hospital, UK.	To assess whether changes in food selection and in perceptions of chewing ability occurred in edentulous patients following the provision of implant and conventional prostheses.	RCT	83	N/A	Baseline and 3 months later	Prosthetic treatment (Treatment Allocation: 3 groups ((i) Requested and received implants (n=26), (ii) requested implant prostheses, but received CDs (n=22), and (iii) requested and received CDs (n=35))
Awad (2012)	Montreal, Canada	To determine whether providing simple mandibular implant overdentures (IODs) to elderly individuals would give them a significantly better nutritional profile than those who receive complete dentures (CDs).	RCT	255 (CD=128: F=71, M=57; IOD=127: F=70, M=57)	≥65 yrs/ healthy, independently living, have been edentulous for >5 yrs and with sufficient bone for placement of 2 implants in the anterior mandible.	Baseline, 6 months and 12 months post-treatment.	Prosthetic treatment
Borges (2011)	Brazil	To compare masticatory performance and the nutritional condition of conventional complete denture wearers before and after conversion of the lower prosthesis into an overdenture retained by two implants with an immediately loaded bar-clip, as well as the association between masticatory performance and nutritional condition.	Matched-pairs clinical study	16	30–76 yrs (average 59·2 yrs). 62·5% of the subjects were elderly (>60 yrs).	Baseline, 3 and 6 months post-treatment	Prosthetic treatment

Table APP4 (Cont.): Articles that reported on the relationship between IODs, CDs and nutrition

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
de Oliveira (2004)	Sao Paulo, Brazil	To assess the possible risk of malnutrition among the elderly population.	Cross-sectional	40 (CD=23, IOD=17)	Elderly (No specific age was mentioned in the article). Participants randomized to the IOD group had either a bar-clip or an O-ring system to support the overdentures.	Baseline and then 12 months	Prosthetic treatment
Ellis (2010)	Newcastle upon Tyne, UK	To compare the impact of customised dietary advice on patients' satisfaction with their dentures and oral health-related quality of life (OHRQoL) in patients wearing IODs or conventional CDs.	Prospective clinical study	54 (CD=26: F=18, M=8; IOD=28: F=20, M=8)	The CD group mean age = 70.6 yrs (±10.9 yrs) and was significantly older (P=0.035) than the IOD group, which had a mean of 65.4 yrs (±8.8 yrs)/ All participants have had their prosthesis provided 3 months to 5 years before the beginning of the study, healthy and independently living.	Baseline and 6 months following provision of customised dietary advice.	Prosthetic treatment
Ellis (2008)	UK	To conduct a randomized-controlled trial to compare food choices of edentulous adults provided with IODs and conventional CDs.	RCT	97 (CD=48: F=34, M=14; IOD=49: F=35, M=14)	<80 yrs, CD group mean age = 68.07 (STD 10.09 yrs) and the IOD group = 64.67 (STD 9.9 yrs)/ healthy/ edentulous for >5 yrs and with sufficient bone for placement of 2 implants in the anterior mandible.	Data were collected pre-treatment and 3 months post treatment.	Prosthetic treatment
Gjengedal (2012)	Bergen, Norway	To assess and compare the dietary intake in two groups of edentulous adults dissatisfied with their existing mandibular denture; one group had their dentures conventionally relined, while the other had their mandibular dentures converted into IODs.	RCT	53 (CD=26; IOD=27)	<76 yrs of age, dissatisfied with their mandibular complete denture opposed by a maxillary conventional complete denture, the lower denture is of acceptable technical quality,	24-h recalls (baseline, 4, 8, and 11 months); self-administered questionnaire (baseline, 3, 6, 12 and 24 months).	Prosthetic treatment

Table APP4 (Cont.): Articles that reported on the relationship between IODs, CDs and nutrition

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Hamada (2001)	Los Angelos, USA	To compare the pre-treatment and post-treatment diets of edentulous controlled diabetic patients who received new dentures with either a mandibular CD or an IOD supported by 2 implants connected with a Hader bar.	RCT	58 (CD=21; IOD=37)	>50 yrs (Range = 48-75 yrs)/ patients with acceptable control of diabetes. 2 similar groups in educational levels, 18 medical conditions, smoking habit, use of 14 of the 15 classes of medications or denture experience.	Baseline and 6 months post-treatment	Prosthetic treatment
Morais (2003)	Montreal, Canada	To test the hypothesis of no difference in nutritional status between patients with mandibular IODs or with CDs at 6 months post-treatment.	RCT	56 (CD=27: F=17, M=10; IOD=29: F=15, M=14)	65-75 yrs/ healthy, independently living, edentulous for >5 yrs, sufficient bone for 2 implants in the anterior mandible.	Baseline and 6 months after treatment.	Prosthetic treatment
Moynihan (2012)	Newcastle upon Tyne, UK	To compare the effectiveness of a tailored nutrition intervention aiming to increase the intake of fruits, vegetables and fibre between patients wearing CDs and patients with IODs.	A two cohort prospective parallel dietary intervention study.	54 (CD=26: F=18, M=8; IOD=28: F=20, M=8)	40-80 yrs/ non-diabetic, good general health, independently living, for the IOD group prosthesis made >3 months and <5 yrs.	Baseline as well as 3 and 6 months post-dietary intervention.	Prosthetic treatment
Muller (2008)	Montreal, Canada	To evaluate the nutritional status of edentulous patients who randomly received either a CD or an IOD 1 year previously.	Cross-sectional	53 (CD=24: F=8, M=16; IOD=29: F=14, M=15)	Mean = 53 yrs (range: 41-70 yrs)./ healthy, independently living regular CD wearers, have been edentulous for >10 yrs.	12-14 months post treatment.	Prosthetic treatment
Neto (2012)	Natal, Brazil	To evaluate the masticatory efficiency of patients rehabilitated with CDs or IODs retained by two splinted implants with bar-clip system.	RCT	29 (CD=15: F=11, M=4; IOD=14: F=9, M=5)	Average = 65.5 yrs (STD 6.7 yrs)/ healthy, independently living, fully edentulous who had previously worn dentures and required a new set of dentures	3 months after denture insertion.	Prosthetic treatment
Roumanas (2003)	Los Angelos, USA	To determine whether chewing difficulty of consumed foods is altered by the replacement of existing CDs with either a mandibular CD or an IOD.	RCT	58 (CD=21, IOD=37)	Mean age= 66.0 yrs (STD 5.9)/ Participants with controlled diabetes managed with or without insulin	Baseline and 6 months post-treatment	Prosthetic treatment

Table APP4 (Cont.): Articles that reported on the relationship between IODs, CDs and nutrition

First Author (Year Published)	Study Location	Study Objective(s)	Study Description/ Design	Sample Size	Age Range/ Population Characteristics	Evaluation Period	Primary Classification
Sanchez-Ayala (2010)	N/A	To present all studies that have evaluated, with valid scientific methodology, the physical and nutrient intake improvement of subjects with removable and supported or retained implant denture, compared with those wearing CDs.	Systematic review	N/A	>50 yrs/ All study participants included in this review were without syndrome and systemic influences, nor presenting surgical or other simultaneous treatment, which could affect the integrity during the evaluation period.	N/A	Prosthetic treatment
Sandstrom (1987)	Gothenburg, Sweden	To analyze the long-term effects on dietary habits and food selection before, during, and after restoration of masticatory ability, as achieved by optimizing the CDs or inserting mandibular IODs.	Prospective comparative clinical study	23 (F=17, M=6)	40-65 yrs	78 months after treatment	Prosthetic treatment
Sebring (1995)	Washington D.C., USA	(1) To ascertain whether nutrient intake in edentulous individuals changed after receiving new IODs or new CDs; (2) To determine differences in reported nutrient intake between groups after treatment; (3) to assess the nutritional adequacy of self-reported intakes.	Prospective clinical study	71 (CD=31: F=19, M=12; IOD=40: F=25, M=15)	Mean (CD-M)= 60.2 yrs (STD 11.5); mean (CD-F)= 60.3 yrs (STD 9.5); mean (IOD-M)= 55.5 yrs (STD 8.7); mean (IOD-F)= 58.8 yrs (STD 11.5)/ A convenience sample of completely edentulous individuals, who had previously been provided with dentures for a minimum of 1 year.	Baseline, and then semi-annually until 36 months post-treatment.	Prosthetic treatment.
van Kampen (2004)	the Center for Special Dental Care at the Central Military Hospital in Utrecht, Holland	To test the hypothesis that mandibular conventional denture treatment, implant-supported overdenture treatment, and attachment type affects masticatory performance and efficiency as well as swallowing threshold.	Within-subject cross-over clinical trial.	18 (F=1, M=17)	Mean = 51.6 yrs (range = 33 to 56 yrs)/ participants from the Royal Dutch Army, fit for military service, and had been edentulous in the mandible for an average of 18 yrs. All participants were treated with 2 mandibular implants using 3 suprastructure modalities.	14 months	Attachment type of the overdenture

ANNEXES

ANNEX I

ADDITIONAL TRIAL DETAILS

1. The Trial Design

This was a randomized, controlled parallel trial. Neither the subjects nor the treating clinicians could be blinded to treatment allocation. However, data were gathered, measured, recorded and entered by nurses and technicians who were blind to treatment allocation.

2. Details on the Trial Interventions

Control - Maxillary and mandibular conventional dentures.

Conventional dentures for the maxilla and mandible will be fabricated in a standard manner.

Experimental **-** Maxillary conventional denture and mandibular overdenture prostheses on two implants with ball attachments.

Two transmucosal titanium implants (Straumann - 048.242/243) were implanted using a standard protocol into the canine region of the anterior mandible. The old dentures were worn for two weeks following the surgery. They were then relieved around the emerging implants and relined with soft material. Subjects were instructed to chew soft foods, and they were monitored during the healing

period. After healing for 3 months, subjects received new complete dentures in both jaws; a maxillary conventional denture and a mandibular overdenture that rests on ball retainers.

3. Practical Arrangements for Allocating Participants to Trial Groups

Advertisements for subjects who were willing to participate in a clinical trial of mandibular conventional dentures or 2-implant overdentures were placed in a local French and English newspaper, as well as in a monthly periodical for retired people. Based on past experience, these advertisements were read by a large number of potential subjects. Respondants were asked to telephone a dedicated number with a voicemail. The research assistants returned the phone calls, described the study (purpose, location, number of appointments, length of study, random allocation to treatment, etc.). They then determined if each potential subject met the demographic inclusion criteria and invited him/her to an information session, in which all aspects of the treatments and the study were explained by the research assistant using overheads and slides. Descriptions of the project were provided verbally and in writing to each potential subject. The Prosthodontic and Surgical Coordinators, Klemetti and Chehade, then responded to all questions concerning the treatment. The consent form was handed out and read to the group by the research assistant, who answered all questions raised. Patients were then examined by the clinicians. Each patient meeting the eligibility

criteria was then individually asked if s/he wished to participate and, if so, was invited to sign the consent form. Once eligibility and consent have been confirmed, treatment assignment was obtained by the research assistant from the randomization center. The research assistant informed the patients of their treatment assignment and appointment date by telephone. Treatment group was randomly assigned using a computer generated permuted block scheme. Varying block sizes were used to preserve allocation concealment and reduce any potential selection bias.

4. Methods for Protecting Against Other Sources of Bias

All persons interacting with subjects were told not to comment on the two therapies. Because more than one clinician participated in the trial, potential operator effects were balanced by assuring that an equal number of subjects in both groups were treated by each of the clinicians. Subjects received all questionnaires from the research assistant (RA) in a secluded area away from the clinic and the care provider.

It was not possible for the subjects or the treating clinicians to be blind to treatment. However, data were gathered by a research nurse who was not involved in providing the treatment. She was instructed not to discuss treatment type with the subjects, who were asked not to discuss their treatment with the nurse. Data were entered by a RA who was blind to treatment assignment.

5. Detailed Inclusion/ Exclusion Criteria

All potential subjects completed a medical history, which included questions about their present oral condition, general health and use of medications. They also completed questionnaires on oral function, so that we could assess their ability to understand and use the measures that were employed in the study. Potential subjects were also given the Mini-Mental State Evaluation to screen for impaired cognitive function [141]. Those who score 24 or less were excused from the screening process [142], as memory must be intact to provide accurate 24-hour dietary recall information. The clinicians determined if there was sufficient bone in the anterior mandible, chronic mucositis, hyperplasia, or other conditions that would complicate prosthetic treatment. Patients with specific clinical conditions were excluded (see exclusion criteria), as well as those with BMI below 20 or above 32 kg/m^2 because they might have conditions that would interfere with the interpretation of the data. However, the allowable range includes the large majority of the elderly population, since normal BMI range is between 22 - 29 kg/m [143]. Patients taking dietary supplements (about 10% of the population) were excluded since these may compensate for deficiencies in the blood parameters under study (see section 8: "The Proposed Primary and Secondary Outcome Measures"). In addition, anyone taking anti-neoplastic medication, phenytoin or corticosteroids were excluded, as these affected blood nutrient concentrations.

Inclusion Criteria

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

Exclusion Criteria

- Insufficient bone to place two implants in the anterior mandible
- Other oral conditions that preclude immediate prosthetic treatment
- Acute or chronic symptoms of temporomandibular disorders
- History of radiation therapy to the orofacial region
- Systemic or neurologic disease that contraindicate implant surgery
- Any neoplasia diagnosed less than 5 years previously
- Uncontrolled diabetes or other metabolic diseases which could affect the normal healing process
- Uncontrolled hematologic and immunologic diseases
- Chronic use of systemic steroids
- A BMI less than 20 or more than 32 kg/m^2

- Score of 24 or less on the Mini-Mental State Evaluation (to eliminate subjects with impaired cognitive function)
- Presently taking any of the following which will affect blood nutrient concentrations: dietary supplements, anti-neoplastic medication, phenytoin or corticosteroids
- Other health conditions that jeopardize surgical treatment (alcoholism, etc.)
- Psychologic or psychiatric conditions that could influence diet and reaction to treatment.

6. Duration of Treatment Period

For an individual patient, conventional denture treatment requires approximately two months, while implant treatment takes approximately 5 months. The treatment in this study was carried out over a 2.5-year period.

7. Frequency and Duration of Follow-up

Data were gathered at baseline, then 6 and 12 months after treatment for each subject. Many nutritional intervention studies gather data at 6 months, as it is believed that all potential benefits, including changes in body composition measurements, are evident by this time [144,145]. We repeated the measures at 1 year to confirm that the changes are persistent [146].

8. The Proposed Primary and Secondary Outcome Measures

Primary Outcome

Blood Serum Concentration of Homocysteine [tHcy]: We choose as our primary outcome a marker of general good health, plasma homocysteine concentration [tHcy]. [tHcy] is sensitive to changes in dietary intake of fresh fruit, vegetables and meat, and is related to disease. High [tHcy] is associated with cardiovascular disease in the general population [147], cognitive dysfunction in the elderly [148] and neural tube defects in pregnant women [149]. Furthermore, high [tHcy](>14.4 µmol/L) is associated with twice the risk of carotid stenosis, compared with low [tHcy] (9.1 µmol/L), after correction for other factors [150]. It has been estimated that an increase in [tHcy] of 1 µmol/L is associated with a 10% increase risk of cardiovascular disease [151]. Given that 1) patients with mandibular overdentures are able to chew harder foods and thus are capable of eating more meat, fresh vegetables and fruits than conventional dentures wearers and 2) our previous observation of a significant increase of plasma concentrations of vitamin B12 in an implant overdenture group, this healthier dietary habit should translate into a decrease of plasma [tHcy].

Secondary Outcomes

I. **Blood serum concentrations of:** Albumin, Carotine, vitamin B-12, vitamin B-6, and RBC folate.

II. **Dietary intake:** The 24 hour recall was done in person at baseline to assess portion size using food models. Two further recalls at 6 and 12 months were done by telephone. This has been successful in earlier studies [152] in which no differences in mean intake between days of face-to-face vs. telephone contact were found. Interviews were done by dietitians who followed a training program offered by the Food Habits of Canadians Dietary Assessment Group, an FRSQ team headed by Gray-Donald. The Group runs dietary survey and validation studies. All data entry and food and nutrient analysis were done using specific software (CANDAT, G. Godin and Assoc., London, Ont).

III. **Function**

IV. **Clinical Measures of Oral Health**

V. **Health-related quality of life (QoL)**

VI. **Physical activity**

VII. **Depression**

9. Problems with compliance

Compliance with treatment was not a problem in our earlier trials nor was it a problem in this study. All subjects were seeking treatment and are accustomed to wearing prostheses. Each received a personal letter at the beginning and middle of the trial, discussing the importance of the data that they provided. Visits for

data collection coincided with follow-up clinical appointments. Subjects were paid $25 per follow-up session to compensate transportation and parking costs.

ANNEX II

SURGICAL PROTOCOL

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

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

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

ANNEX III

24-HOURS DIETARY RECALL FORM (EXAMPLE)

24-HOUR RECALL

Interviewer Initials: [illegible] **Subject Code:** JK 00140

Interview Date: 10 / 9 / 03 (dd mm yy) **Recall Number:** (1) 2 3

Day of the Week: 1 M, (2) T, 3 W, 4 T, 5 F, 6 S, 0 S

Time Started: 950 **Time Ended:** 9[illegible]

Time	Description of Food Eaten and How Prepared	Amount Eaten
700	Minute Maid orange juice from frozen with pulp	1/2 c.
	cottage cheese 1%	250 g
	grapes seedless green	3/4 [illegible]
	Coffee instant	2 c
	↳ nescafé	2 tsp
	regular carnation milk [illegible] evaporated	2 Tbsp
	brown sugar	1 Tbsp
1000	Cheerios multigrain	1 c
	skim milk	3/4 c
	hot chocolate	
	↳ water hot	1 c
	[illegible] hot chocolate [illegible]	17.5 [illegible]
100	Salmon salad	1 c
	canned salmon [illegible]	
	regular mayo	
	[illegible] pepper	
	capers	
	tomato "V" [illegible]	1 whole
	Cranberry juice Ocean Spray (cocktail)	1 c
400	Coffee as above	1 c
500	Herring fillets in wine sauce (Feature brand in jar)	[illegible]
	St. Viateur bagel [illegible]	1 whole
	Margarine "Celeb" 70% canola	2 Tbsp
	Cheddar cheese [illegible] extra old	2 oz
	[illegible] Quaker [illegible] cheddar flavour [illegible]	16 pieces
	toasted 9 grain bread from Costco	2 slices
	WATER 2 x 1 1/4 c	

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See next page

☑ Baseline
☐ 6 months
☐ 12 months