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**To Investigate Whether a Diagnostic Classification of
Edentulism Relates to Oral Health Related Quality of Life,
Nutritional Status and Denture Satisfaction**

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**A thesis submitted in accordance with the regulations for the degree of
D.Ch.Dent. at the University of Dublin, Trinity College**

July 2012



TX-1-945

DECLARATION

- I hereby declare that this thesis has not previously been submitted for a degree at this or any other university and that it represents my own work.
- I acknowledge assistance from Ms. Laura Schwirz and Dr. Alan Kelly in relation to statistical analysis.
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Laura Kelly

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SUMMARY

Statement of the problem: Currently there is no way of objectively predicting patient satisfaction or response to treatment of edentulism. There is a lack of evidence relating traditional diagnostic criteria to outcomes of treatment.

Purpose: This study sought to investigate if diagnostic complexity of edentulism relates to oral health related quality of life (OHRQoL), nutritional status and denture satisfaction. Further, to identify whether new conventional complete dentures have an impact on OHRQoL or denture satisfaction. Finally, to investigate if conventional complete dentures impact on OHRQoL and denture satisfaction to varying degrees depending on an individual's diagnostic classification.

Materials and Methods: 46 participants were recruited between September 2010 and April 2012. A clinical examination was conducted to classify participants according to the American College of Prosthodontists' checklist for classification of complete edentulism (ACP-PDI). Participants completed three questionnaires (Oral Health Impact Profile – edentulous (OHIP-EDENT), Mini Nutritional Assessment – Short Form (MNA-SF) and Denture Satisfaction Questionnaire (DSQ)). The patient generated responses were compiled as numeric data and entered into an electronic database. STATA version 12 statistical package for Windows was used to analyse results. Parametrical tests for the comparison of averages (paired t-tests, independent t-tests and two group mean comparison tests) were used to compare levels of impact and satisfaction among different groups. A p-value <0.05 was

considered as statistically significant. To explain variation in the dependent variable (ACP classification of edentulism) with respect to the independent variables (OHIP-EDENT, MNA-SF and DSQ) a logistic regression analysis was conducted.

Results: Two group mean comparison tests found no significant differences between varying levels of diagnostic classification at baseline with respect to OHIP-EDENT, MNA-SF and DSQ total scores. There was a significant association between diagnostic complexity and the response to DSQ 1 “In general are you satisfied with your lower complete denture?” A statistically significant improvement in total scores for all questionnaires was observed following complete denture provision (using paired t-tests for OHIP-EDENT and DSQ). For this improvement following conventional denture treatment, no significant difference was found between groups of anatomical complexity using independent t-tests for OHIP-EDENT and DSQ.

Conclusion: This study observed no difference in self reported status between edentulous patients who were rated less or more orally compromised, according to an objective scale of oral condition (ACP-PDI). All patient based outcomes measured in this study improved following provision of complete dentures. Both groups of patients responded similarly to the provision of complete dentures, according to the subjective assessment of their status.

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This thesis is dedicated to my family especially mum and dad who have been a constant source of support and encouragement throughout my career. I am grateful also for two fabulous sisters whose own success has inspired my life and who are always there for me.

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Abbreviations

ACP	American College of Prosthodontists
ALARA	As Low As Reasonably Achievable
BDI	Beck depression inventory
BMI	Body Mass Index
CAT	Category Scales
DDUH	Dublin Dental University and Hospital
DIDL	Dental Impacts on Daily Living
DIP	Denal Impact Profile
DLQI	Dermatology Life Quality Index
DPI	Dots per Inch
DSQ	Denture Satisfaction Questionnaire
G8	Group of Eight
GHQ	General Health Questionnaire
HADS	Hospital Anxiety and Depression Scale
GOHAI	Geriatric Oral Health Assessment Index
ICIDH	International Classification of Impairments Disabilities and Handicaps
KFS	Karnofsky Performance Scale
M	Mean
MNA	Mini Nutritional Assessment
MNA-SF	Mini Nutritional Assessment - Short Form
NICE	National Institute for Health and Clinical Excellence
NHP	Nottingham Health Profile
OHRQoL	Oral Health Related Quality of Life
OHIP	Oral Health Impact Profile
OHIP-EDENT	Oral Health Impact Profile – Edentulous
OHIP-WS	Oral Health Impact Profile – weighted statements

OHIP-14	Oral Health Impact Profile – 14
OHIP-49	Oral Health Impact Profile – 49
OIDP	Oral Impact on Daily Performance
OLS	Ordinary Least Squares
PBO	Patient Based Outcomes
PCA	Principle Components Analysis
PDI	Prosthetic Diagnostic Index
QoL	Quality of Life
QWB	Quality of Well Being Scale
SD	Standard Deviation
SEIQoL	Schedule for the evaluation of individualised quality of life
SIDD	Social Impacts of Dental Disease
SIP	Sickness Impact Profile
US	United States
WHO	World Health Organisation

Study objectives

- To investigate if the complexity of diagnostic classification of edentulism relates to
 - oral health related quality of life
 - nutritional status
 - denture satisfaction

Null hypothesis: There is no association between complexity of diagnostic classification of edentulism and oral health related quality of life, nutritional status and denture satisfaction.

- To identify whether new conventional complete dentures have an impact on
 - oral health related quality of life
 - nutritional status
 - denture satisfaction

Null hypothesis: Conventional complete dentures have no impact on oral health related quality of life, nutritional status and denture satisfaction.

- To investigate if new conventional complete dentures have a varying level of impact according to diagnostic classification on
 - oral health related quality of life
 - nutritional status
 - denture satisfaction

Null hypothesis: Conventional complete dentures observe no varying level of impact according to diagnostic classification regarding oral health related quality of life, nutritional status and denture satisfaction.

Chapter 1

Introduction

1. Introduction

1.1 Edentulism

Edentulism is defined as the loss of all permanent teeth [1]. It is a broad spectrum of disability with varying quantities and dimensions of supporting bone loss, positioning of muscle attachments and associated anatomical and physiological impairments. The diversity observed in an edentulous population means the condition cannot be adequately described by a single diagnosis. The WHO International Classification of Impairments Disabilities and Handicaps (ICIDH) [2] has three distinct parts; impairment (the impact of the condition on the body), disability (the impact of the condition upon the person) and handicap (the impact of the condition upon the person interacting with the environment) [2, 3]. Edentulism has a significant impact on daily oral function and social interactions and has been described from multiple perspectives. Edentulism can be described as an impairment due to anatomic loss, a handicap because of social disability (e.g. having to decline social invitations due to embarrassment with dentures) and a disability due to lack of ability to perform the tasks of daily living (e.g. inability to eat certain foods).

1.1.1. Incidence of edentulism

Edentulism is an international problem; a prevalence of 48.3%, 56.6%, 65.4% and 71.5% has been reported in Ireland, Malaysia, the Netherlands and Iceland respectively [4]. The reported prevalence of edentulism ranges from 1.3-78.0% for those older than 65 years of age [5].

Twenty six per cent of the United States (US) population between 65 and 74 years of age are completely edentulous [6].

1.1.2. Demographics of patients with edentulism in Ireland

The most recent national survey of the oral health of Irish adults (2000/01) [7] reported edentulism to have fallen dramatically since 1979. This decline was slower between 1989/90 and 2000/01 than the rate of decline previously observed. One percent of 35-44 year olds were edentulous in 2000/01. In 2000/01 more women than men aged over 65 were edentulous but there was no gender difference in other age groups in the same period. Adults with systemic disease had higher levels of edentulism than those without. This is illustrated in *Table 1.1* which shows the number of adults and the percentage who were edentulous, by age group and general health status as indicated by the American Society of Anesthesiologists (ASA) classification. This classification system was developed to assess patients' medical fitness prior to surgery but gives a good indication of general health status and disease control. Medical card holders were significantly associated with having fewer teeth in 35-44 year old and the over 65 year old categories. *Table 1.2* shows the percentage of adults who were edentulous by age group, gender and medical card status in 1989/'90 and in 2000/'02. More edentulous adults were wearing dentures in 2000/01 than in 1989/90. Amongst those aged 65 years and older who were edentulous, 6.0% had no dentures in 2000/01 compared with 21.4% in 1989/90. Forty seven percent of older edentulous adults were wearing dentures which were over 10 years old.

Table 1.1: Percentage of adults who were edentulous by age group, gender and medical card status in 1989/'90 and in 2000/'02 [7]

	Medical Card Holders					
	Male		Female		Total	
	1989/'90	2000/'02	1989/'90	2000/'02	1989/'90	2000/'02
16-24 year-olds	0.0	0.0	0.0	0.0	0.0	0.0
35-44 year-olds	3.2	1.2	7.8	1.5	6.3	1.4
65+ year-olds	48.2	40.1	72.2	49.2	62.2	45.6

	Non Medical Card Holders					
	Male		Female		Total	
	1989/'90	2000/'02	1989/'90	2000/'02	1989/'90	2000/'02
16-24 year-olds	0.0	0.0	0.0	0.0	0.0	0.0
35-44 year-olds	2.7	0.1	3.4	0.7	3.4	0.4
65+ year-olds	17.0	23.9	42.9	35.2	30.8	29.4

1.1.3. Aetiology of Edentulism

Edentulism has a multifactorial aetiology with income and level of education appearing to be predictors of edentulism while other factors, such as dental aptitude and access to care, being less directly linked [8]. Low income adults aged over 65 years have the highest rate of edentulism [9]. Many factors are associated with tooth loss and there is no consensus whether dental disease related or socio-behavioural factors are most important in the aetiology of tooth loss [10]. At present, any causal relationship between poor general health and edentulism lacks robust scientific evidence but there are many common risk factors including systemic disease, smoking, poor diet and low socioeconomic status [11].

1.1.4. Treatment of Edentulism

Historically, the provision of conventional dentures was the only treatment modality available to edentulous persons. Conventional complete dentures rely entirely on the anatomy of the residual ridge, along with favourable oral musculature and a suctional seal from a thin layer

of saliva for retention. Conventional complete denture therapy is not without associated complications. These include denture stomatitis, traumatic ulcers, irritation-induced hyperplasia, altered taste perception and gagging [12]. It often arises that even when dentures are judged to be excellent objectively, many patients cannot eat certain foods or speak clearly because of failure to adapt [13]. Prosthetic treatment, which may be technically correct, may be a clinical failure by virtue of the fact that the patient is dissatisfied with the outcome.

Almost 10 years after the Mc Gill consensus statement on overdentures in 2002 [14], which recommended a two-implant retained mandibular overdenture as the standard of care in an edentulous mandible, this has not routinely become a clinical reality. This recommendation was based on expert opinion at the time, but there is no evidence to suggest all edentulous persons will benefit from a two-implant retained mandibular overdenture.

1.1.4.1. Patient Centred Outcomes in Treatment of Edentulism

Tooth loss is an irreversible process. Hence, the main goal of therapies for edentulism is improvement in the condition rather than cure, thus patient focused outcomes are important [15]. Anderson in 1998 [16], proposed a broader, more comprehensive evaluation of prosthodontic outcomes which he divided into four categories:

1. Biological and physiological parameters (health of oral structures, chewing ability, nutritional status, aesthetics)
2. Longevity and survival (of teeth, implants, restorations)
3. Psychosocial parameters (treatment satisfaction, self esteem, body image and quality of life)

4. Economic parameters (cost of fabrication and maintenance etc).

1.1.5. Classification of edentulism

Considering all edentulous patients as a single group fails to take account of the wide range of physical variation seen within these individuals. A subcommittee on prosthodontic classification within the American College of Prosthodontists (ACP) was established in 1994, and in 1999 they described a diagnostic index for edentulism using specific diagnostic criteria [17]. A graduated classification system for complete edentulism based on diagnostic findings was developed (*Figure 2.1*). Four categories were identified ranging from class I (the least complicated clinical situation) to class IV (the most complex and challenging situation). This classification tool was found to be able to identify, quantify and measure varying degrees of compromise in edentulism consistently and across all calibrated groups [18]. It is considered that pre-prosthetic surgery was required for classifications III and IV and in circumstances where surgical revision was not possible, specialised prosthodontic techniques should be employed [19].

Pan et al [20] investigated the relationship between clinical assessment of the level of difficulty in providing conventional treatment (guided by the ACP classification for edentulous patients) and patients' rating of their denture satisfaction. The authors reported that while the ACP assessment tool could be used reliably and demonstrated good intra- and inter-examiner reliability, there was no significant correlation between classifications and patients' denture satisfaction.

1.2. Quality of Life

Quality of Life (QoL) is defined as an individual's perception of his or her position in life, in the context of culture and value systems in which they live and in relation to their goals, expectations and concerns [21]. The concept of QoL was developed as an objective indicator and has been in use in both medical and sociological research for over 30 years. Through the use of a validated questionnaire, patients rate their actual situation relative to their personal expectations. Health care resources can be better allocated with a more informed understanding of behavioural and psychological sequelae of therapies [22]. Health related QoL is defined in relation to the optimum levels of mental, physical and social functioning including relationships, perceptions of health, fitness, life satisfaction and well being [23]. For chronic diseases, the main aim of treatment is an improvement in QoL and it is increasingly thought that patients should have an active role in the decisions about their health care. QoL is increasingly becoming accepted as one of the most important outcome measures in the evaluation of any treatment or health-related intervention [24]. For example, the national institute for health and clinical excellence (NICE) based a decision on which drug to use in treating psoriasis using the dermatology life quality index (DLQI) severity criteria [25]. Alitretinoin had a score of 15 which compared favourably with most biologics used for psoriasis (score of 10). A choice of alitretinoin over more costly biologic drugs proved more cost effective while being equally effective in disease control.

It is not uncommon to observe statistical anomalies during QoL data analysis. Common examples include the ceiling effect, floor effect and response shift bias. The ceiling effect is seen when patients present with higher than average QoL and there is limited room for improvement following an intervention. The opposite, called the floor effect, is refers to

when data cannot take on a value lower than some particular number, called the floor. Further, the floor effect is seen when inappropriate QoL instruments are used with inclusion of questions irrelevant to the population being studied. This has the effect of the data all hitting the bottom end of the distribution. Both phenomena have the potential to skew the results. Response shift bias occurs more commonly in longitudinal studies which use patient reported outcomes. Participants' views, values or expectations can change over the course of the study. This affords the opportunity to evaluate what type of change is occurring and why.

1.2.1. Measuring Quality of Life

The WHO definition of health in the context of disease (physical, mental and social), is considered to be one of the earliest references to QoL [26]. Shortly after, Karnofsky and Burchenal [27] developed the Karnofsky Performance Scale (KFS). This instrument had a percentage scale ranging from "0-dead" to "100-normal without complaints or evidence of disease". Following on from this, Sickness Impact Profile (SIP) [28] and Nottingham Health Profile (NHP) [29] were developed. These measures were broader than KPS, addressing psychological and physical symptoms, physical function, the impact of an illness as well as life satisfaction and perceived distress. Since then multiple instruments to measure QoL have been developed.

QoL measures can be considered in terms of i) unidimensional or ii) multidimensional measures. Unidimensional measures focus on one particular aspect of health. Examples include; the hospital anxiety and depression scale (HADS) [30], the Beck depression inventory (BDI) [31], both of which are concerned with mood and the McGill pain

questionnaire which assesses pain level [32]. Multidimensional measures assess health in the broadest sense. This does not always infer a long complex process. Often, a single item such as “Rate your current state of health” can be used. Although these simple measures do not provide detailed information, they do correlate highly with other more complex measures and have been shown to be useful as an outcome measure [33].

Disease specific questionnaires can be used to:

- Assess and monitor disease burden
- Identify patients whose disease is poorly managed
- Tailor treatment strategy to match disease severity

Disease specific questionnaires are focused on a particular condition or disease. For example, HeartQoL was designed to develop a single reliable and valid core coronary heart disease-specific, health-related QoL questionnaire.

Individual quality of life measures have been developed which not only ask participants to rate their own health status but also to define the dimensions along which it should be rated. The schedule for evaluation of individual quality of life (SEIQoL) [34, 35] first identifies domains of a respondent’s life that he or she considers to be most important to their overall QoL. Respondents then rate their level of functioning in each domain and the relative importance of each domain is subsequently measured using a technique called judgement analysis. Judgement analysis measures patients’ level of functioning in five self-nominated facets of life and the relative weight or importance attached to these areas. A study by

O'Boyle et al [35] which looked at the individual quality of life in patients undergoing hip replacement applied SEIQoL with other traditional measures of health status in a prospective study of 20 patients undergoing hip replacement. Findings highlighted the individuality in patient response as well as demonstrating that SEIQoL provides a means by which this can be scientifically assessed. SEIQoL may prove useful in determining the impact of response shift on the assessment of treatment effects in clinical trials.

QoL questionnaires are constantly evolving with disease specific short forms emerging. Short forms simplify administration of the questionnaires and reduce the tendency to floor effect by elimination of questions which are irrelevant to the population being studied.

1.2.2. Measuring Quality of Life in Oral Health

Cohen and Jago (1976) [36] originally acknowledged the difference between quality of life and oral health related quality of life (OHRQoL). Since then, numerous studies have highlighted the impact that oral diseases have on daily life [37, 38]. OHRQoL measures can provide more detailed information for patients who have debilitating oral conditions than generic QoL measures offer.

Oral Health Related Quality of Life (OHRQoL) is defined as an individual's assessment of how the following affect his or her well being: functional factors, psychological factors, social factors and experience of pain/discomfort in relation to orofacial concerns [39]. It measures the relevance and impact of oral health on everyday life using previously validated

self reported questionnaires [40]. Numerous oral health specific measures have been developed over the last 20 years. Oral health is defined as freedom from chronic facial pain; oral and pharyngeal cancers; oral soft tissue lesions; birth defects such as cleft lip and palate; and other diseases affecting the oral, dental and craniofacial tissues, collectively known as the craniofacial complex [41].

Oral diseases are acknowledged to have a broad impact on everyday life with physical, economic, social and psychological consequences. The oral cavity is thought to contribute to QoL through enhancing self-esteem, self-expression, communication and increased facial aesthetic value. Early definitions of this concept limited it to the functioning of the oral cavity and subjective perceptions of pain and discomfort [42]. Within a decade this definition had evolved to encompass a more comprehensive model of OHRQoL focusing more on the individual than on the oral cavity and the way in which oral conditions impact upon well-being [43].

In 1988, Locker proposed a conceptual framework (*Figure 1.2.2.-1*) [44] for measuring oral health based on the WHO ICIDH [45]. With this model of oral health, a means of exploring the impact of oral diseases on QoL was possible. Subsequently it has been acknowledged that, due to the coping skills of individuals, impairment does not always lead to disability and dysfunction does not always result in handicap [46]. Since 1988, several measures of QoL in oral disease have been developed. Some of the more commonly used measures of OHRQoL are given in *Table 1.3* with a listing of impacts they relate to.

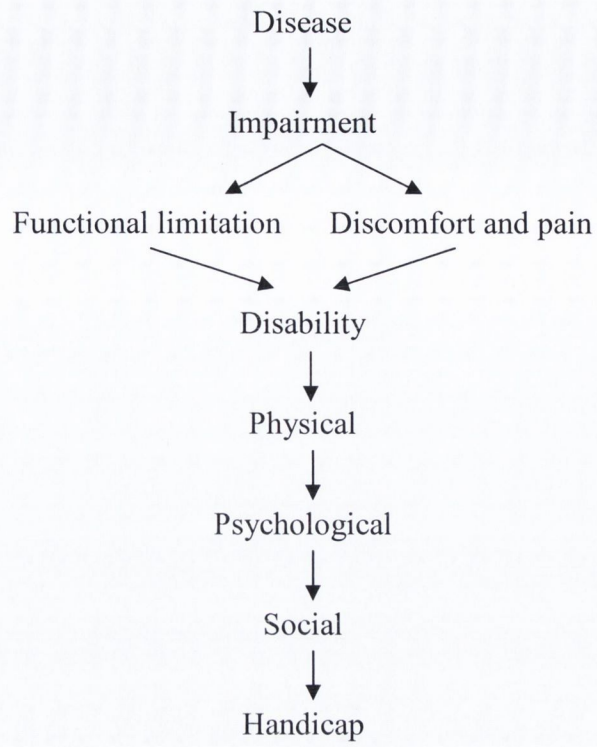


Figure 1.1. Locker's conceptual model of oral health

Table 1.2: More commonly used measures of OHRQoL [47]

Measure	Authors	Impacts
Social Impacts of Dental Disease (SIDD)	Cushing et al 1986	Functional: eating Social interactions: communication Comfort and well being: pain and discomfort Self image: aesthetics
Dental Impact Profile (DIP)	Strauss 1988	Eating:chewing and biting, food choice Health/well being: feeling comfortable, appetite Social Relations: facial appearance, speech and breath, confidence around others Romance: social life, having sex appeal, kissing
Geriatric Oral Health Index of Assessment (GOHAI)	Atchison and Dolan 1990 [48]	Eating:limit food due to dental problems, trouble biting and chewing Pain: medication required, sensitive to temperature Social dimension: nervous due to teeth, uncomfortable eating with people, prevented from speaking, worried about teeth, limited contact with people
Oral Health Impact Profile (OHIP)	Slade and Spencer 1994	Functional limitation: difficulty chewing Physical pain: toothache Psychological discomfort: self conscious about the mouth Physical disability: avoiding certain foods Social disability: avoided going out because of dental problems Handicap: financial loss
Dental Impacts on Daily Living (DIDL)	Leao and Sheiham 1995	Appearance: satisfaction with look of teeth Comfort: bad breath Pain: toothache Performance: ability to work/study Eating restriction: ability to chew and bite foods

1.2.2.1. Oral Health Impact Profile

The Oral Health Impact Profile (OHIP) is a “scaled index of the social impact of oral disorders which draws on a theoretical hierarchy of oral health outcomes” [49]. OHIP was developed by Slade and Spencer in 1994 [49] to measure the impact of oral conditions on health related quality of life. Forty nine statements describing sequelae of oral disorders were initially derived from 535 statements from interviews with 64 dental patients. 328 participants used Thurstone’s method of paired comparisons to discern the relative importance of statements within each of seven conceptual subscales. The instrument’s reliability was verified in a cohort of 122 persons aged 60 and older. Internal reliability and test-retest reliability were consistent. Based on the conceptual framework designed by Locker in 1988 [44], OHIP remains the most comprehensive and sophisticated measure of OHRQoL.

OHIP-49 is the original questionnaire which contains the complete 49 statements categorised under seven domains:

- i. functional limitation (e.g. difficulty chewing foods),
- ii. physical pain (e.g. toothache),
- iii. psychological discomfort (e.g. self consciousness),
- iv. physical disability (e.g. avoiding foods),
- v. psychological disability (e.g. embarrassment),
- vi. social disability (e.g. difficulty doing jobs) and
- vii. handicap (e.g. total inability to function).

QoL is a multidimensional concept and these domains capture the various dimensions of QoL.

As a research tool, OHIP has a high ability to differentiate between different population groups, demonstrates good internal reliability and has been validated in numerous cross sectional population studies [49, 50]. Responses are structured according to a Likert scale (1=never, 2=hardly ever, 3=sometimes, 4=fairly often, 5=very often), some studies use a scale ranging from 0 to 4.

Administration of the 49 questions included in the OHIP-49 questionnaire is quite a lengthy process, taking up to 20 minutes to complete [51]. Further, many of the questions included are not necessarily relevant to an edentulous population (e.g. Have you had a toothache?). Inclusion of questions which are inappropriate to the population being investigated, reduces the ability of the instrument to detect change following clinical intervention, thereby having a floor effect. Use of the full (OHIP-49) questionnaire in an edentulous population would be susceptible to floor effect.

Slade developed a shorter form (OHIP-14) by using a regression analysis approach to identify a subset of 14 questions from the original 49 [52]. These 14 questions (two from each domain) accounted for 94% of variation in total OHIP scores and had an internal reliability coefficient (α) of 0.88. Two items from each domain were selected because they have been shown to be the most frequently reported within their respective sub-scales. Concerns have been raised that OHIP-14 may not detect improvements following clinical intervention (that

there would be a floor effect) [53]. Further, OHIP-14 does not include an item pertaining to chewing, which was also a concern.

With the advantage that questionnaires report data in a standardised way and hence are objective, comes the disadvantage that detailed explanation of answers is not facilitated with this format. Using a questionnaire format may generate superficial responses with participants simply ticking boxes to expedite completion of the questionnaire. There is no means to evaluate how truthful the respondent is.

1.2.1.1.1. OHIP short form for edentulous populations (OHIP-EDENT)

Allen and Locker [54] developed OHIP-EDENT, a 19 item subset of OHIP-49 for use with edentulous populations. An item impact method of reducing the 49 OHIP items produced similar subsets in Canadian and British populations. OHIP-EDENT has the same 7 domains as OHIP-49 but is a 19 item subset of the original questionnaire, including only statements relevant to an edentulous population. Discriminant validity properties of OHIP-EDENT are similar to OHIP-49 and OHIP-14. Sensitivity to change was assessed by measuring effect sizes for denture satisfaction scores and OHIP summary scores. This questionnaire has been validated in an Irish population and shows less susceptibility to floor effect, but equally susceptible to change as OHIP-49 in this particular group of patients [54].

1.2.3. Oral Health Related Quality of Life and Treatment of Edentulism

Optimising conventional dentures has been shown to improve OHRQoL [55]. A randomised controlled trial observed a greater improvement in OHRQoL scores for edentulous persons with implant restorations than that observed for those with conventional prostheses [56]. Two further randomised controlled trials [57, 58], showed similar findings. In both studies, those aged 35-65 had lower (i.e. better) OHIP scores for the implant group than for those receiving conventional complete dentures. For the older group (aged 65-75), although OHIP scores were lower in the implant group for all of the seven domains, it was only significantly lower for the physical domain. The authors concluded that most probably the difference was that the older group were less likely to be engaging in activities assessed by OHIP.

Only incremental improvement is observed with more complex implant restorations. Therefore, with increasing complexity of treatment a directly proportional increase in patient satisfaction levels is not observed [59]. Patients' eating related QoL is most likely to be enhanced by the functional improvement and increased social confidence offered by implant retained overdentures over their conventional counterparts.

Patients' control over their choice of prosthesis may influence OHRQoL. Allen et al [60] found OHIP scores for edentulous persons wearing complete dentures, who sought but did not receive implant treatment, did not improve following treatment. However, a significant improvement was observed for those who had received their preferred treatment. Allen and McMillan [51] found tooth loss had a significantly greater negative impact on quality of life of subjects requesting implants compared with edentulous adults seeking conventional

complete dentures. Denture problems have a greater impact on OHRQoL in edentulous persons seeking implants than those seeking conventional dentures [61].

Age of current complete dentures, time since first complete denture, number of previous complete dentures and the age at which complete dentures were first provided were found not to significantly influence OHRQoL [62].

1.3. Nutrition

Consumption of a well balanced diet is essential for the prevention of chronic diseases [63]. The development of malnutrition is a gradual process which begins with inadequate food intake followed by deterioration at a biochemical level. There is no gold standard from which to measure malnutrition. Traditionally, nutritional status has been measured by appropriately trained physicians using blood and urine analysis (e.g. serum albumin concentration), dietary diaries and anthropometric measurements. Early detection of malnutrition is essential as it can be difficult to correct nutritional status once it has deteriorated [64].

Nutrition is complex and influenced by many factors, including socioeconomic status, residential status (independent living or institutionalised), general health status, mobility, ability to self feed, ability to carry a shopping bag, access to healthy food choices, level of education, preferences as well as the physical ability to chew healthier foods properly [55, 65-68]. A large study of 629 adults reported that those with more than 20 teeth are more likely to have a normal BMI [69]. Nutritional studies of institutionalised populations eliminate certain confounding factors such as degree of mobility, cooking ability, grocery

shopping or financial constraints from influence. Other relevant factors such as mental health issues (e.g. depression) may be greater in institutionalised populations. The prevalence of malnutrition in free-living elderly is relatively low (5-10%) but amongst those living in nursing homes, homebound or hospitalised, it reaches significantly higher levels (30-60%) [64].

1.3.1. Mini Nutritional Assessment

The Mini Nutritional Assessment (MNA) tool was originally developed to assess nutritional status as part of the standard evaluation of elderly patients in clinics, nursing homes, hospitals or among those who are otherwise frail [70]. Collaborative, multicentre (France, America and Switzerland) research developed, validated and cross validated the MNA [70-72]. It has also been validated in an Irish population [73].

Researchers developing the MNA aimed to achieve the following objectives: [72]

- Define a reliable scale
- Define clear thresholds
- Devise a tool suitable for application by a generalist assessor
- Minimal opportunity to introduce bias by the data collector
- Acceptable to patients
- Low cost of administration.

The MNA is a self administered questionnaire which is patient friendly, inexpensive and requires neither laboratory investigations nor specialist training in nutrition. It takes approximately 10 minutes to complete and the following parameters are assessed:

- Anthropometric measurements (height, weight and weight loss)
- Global assessment (six questions related to lifestyle, medication and mobility)
- Dietary questionnaire (eight questions, related to number of meals, food and fluid intake and autonomy of feeding)
- Subjective assessment (self-perception of health and nutrition)

Validation of the MNA involved a series of 3 studies of more than 600 elderly persons [64].

Two principal criteria guided the validation process:

- 1) a nutritional assessment performed independently by two physicians with training in nutrition. The assessment was based on the patient's clinical record without knowledge of their MNA results and
- 2) a comprehensive nutritional assessment, including a complete assessment of anthropometrics (height, weight, knee height, mid-arm and calf circumferences, triceps and subscapular skinfolds), biochemical markers and dietary intake (3 day food records combined with a food-frequency questionnaire) based on the SENECA study [74].

Sensitivity of the MNA has been measured at 96%, specificity at 98% and it has a predictive value of 97% [75]. High sensitivity is required for screening tests and high specificity confirms presence of disease, in this case malnutrition. A review of studies including over

30,000 elderly subjects screened by the MNA revealed a mean incidence of malnutrition of 1% in healthy elderly in the community, 4% in outpatients/home care, 5% in home living patients with Alzheimer's disease, 20% in hospitalised patients and 37% in institutionalised elderly [70]. A recent systematic review [76], reported that MNA was the most commonly used nutritional screening tool.

1.3.1.1. Mini Nutritional Assessment – Short Form

For ease of use and also to serve as a screening tool for nutritional status, a short form of MNA was developed (MNA-SF) [77]. Items were chosen on the basis of item correlation with the total MNA score, clinical nutritional status, internal consistency, reliability, completeness and ease of administration. MNA-SF was found to strongly correlate with total MNA score. Sensitivity was 97.9%, specificity 100% and diagnostic accuracy 98.7% for predicting undernutrition. Findings from a recent systematic review [76] report that both MNA and MNA-SF are significantly associated with subsequent mortality and have good negative predictive power.

1.3.2. Diet, Edentulism and Prosthetic Status

Edentulism and its association with diet and nutritional status has been extensively studied [78-80] and has been found to be associated with poorer nutrition [81-83]. Multiple factors have been suggested to influence this association including race, age, social status, mobility, education, economic resources as well as the ability to eat, but the exact nature of this relationship remains unclear.

The UK National Diet and Nutrition Survey [80] found edentate individuals had greater difficulty eating a range of foods than their dentate counterparts and had a lower food energy and nutrient intake per day as well as a poor quality diet. Both independently living and persons in institutions were included. Participants underwent a dental examination, an interview, a four day food diary as well as blood and urine analysis. Consumption of vitamin C, niacin, non-heme iron, calcium, protein and non-starch polysaccharides (dietary fibre) was significantly lower in edentate subjects. Mean intake of most nutrients were found to be lower in the institutionalised group except for carbohydrate, non-milk extrinsic sugar and calcium. Although energy needs decrease with age, a number of factors including poor oral health, loss of appetite and illness may compromise energy intake.

An extensive study of over 3000 elderly persons [84] also found edentulism was associated with differences in the nutritional status of well functioning, community dwelling elderly. Tsakos et al [85] found that edentulism contributes negatively and significantly to the ability of low income persons aged 50 years and over in the UK to consume a variety of foods. Even after socio-demographic and behavioural variables were adjusted for, edentate individuals consumed 50.7g fewer fruits/vegetables per day than the dentate. This is in agreement with earlier studies [79]. Consumption of carrots and tossed salads among denture wearers was 2.1 and 1.5 times lower, respectively, than for the fully dentate and dietary fibre was 1.2 times less in a study of US civilian, non institutionalised persons [86]. Serum levels of beta carotene, folate and vitamin C were also lower among denture wearers in this study.

Poor oral status (edentulous without dentures or with a single complete denture) was found to increase mashed food consumption and difficulty eating hard foods as well as decreased eating enjoyment [87]. Results also indicated that poor oral status further put these

institutionalised subjects at higher risk of undernutrition (as assessed by the MNA). An institutionalised population was recruited with the aim of eliminating as far as possible factors other than oral status which could influence nutrition. However, these exclusion criteria may account for the lower incidence of undernutrition observed. This is in agreement with another large scale study [88] (n=2766), which also used MNA-SF and found that dental prosthetic condition is a significant factor regarding nutritional health in the elderly.

People who wear complete dentures show significantly lower chewing efficiency than those with a natural dentition. They have smaller chewing cycles, decreased bite force and muscle activity than their dentate counterparts. Chewing efficiency in this population is limited by retention and stability of the dentures along with pain of the denture bearing tissues [89]. There is evidence to suggest that edentulous persons modify their diets to accommodate this, which may pose a greater challenge in achieving adequate nutrition. Denture related problems are likely to be most severe in long-term edentulous elderly patients, where any dietary restriction could compromise overall nutritional status [90].

Number of remaining teeth has been found to be associated with MNA score [73]. MNA classified 6% of subjects in this study as undernourished and 57% at risk of undernutrition. This is dramatically lower than a mean incidence of malnutrition of 37% in institutionalised elderly as reported by Guigoz [70] and an estimate of 30-60% [91, 92] seen in persons either hospitalised or resident in nursing homes. Loss of natural dental occlusion was identified as a risk factor for malnutrition among community-dwelling frail elderly in a large study of over 700 persons living in 8 cities in Japan [93].

Naturally, many factors other than edentulism may impact on the nutritional status of the elderly e.g. reduced mobility and not having control over the preparation of their food. Even when an older person is living independently, access to purchase nutritious food may be restricted by limited mobility. Prevalence of malnutrition has been estimated at 5-10% in community dwelling elderly while for those either hospitalised or in nursing homes it is estimated at around 21-60% [91, 92]. Family or care givers involved in food shopping or preparing meals for the older adult should be informed about healthy food choices.

To date, there has been no investigation of any possible association between diagnostic complexity and nutrition. It appears intuitive that there could be a link between these two factors and merits further investigation.

1.3.2.1. Influence of treatment modality on nutrition

Much research into the effect of prosthetic rehabilitation on nutrition has related to clinical outcomes and improvement in functional status [65, 83, 94, 95] However, the patient experience when eating with dentures is of importance also. Patients' comfort and confidence with their dentures can impact other areas of their lives such as their ability to socialise [96]. No association has been found between diet and oral health related quality of life (OHRQoL) [66]. The available literature is inconsistent regarding the influence that the type of treatment modality for complete edentulism has on nutritional status.

Patients who first received conventional complete dentures followed by implant retained overdentures demonstrated only a slight increase in bread and fruit consumption with the latter [95]. Comparing one group with conventional dentures to another with implant retained overdentures demonstrates no significant differences regarding nutrient intake after treatment

[97]. This is in agreement with other studies which have shown that providing implant restorations does not radically alter diet [95, 97, 98]. A randomized controlled trial of food choices looking at a cohort of patients randomly assigned to conventional denture and implant overdenture treatment groups found no significant difference between the groups after treatment and no noticeable increase in the numbers who could eat hard foods (nuts, apples and carrots) [67]. Both groups showed a significant improvement in the scope of their food choices following treatment.

Other evidence suggests implant retained overdentures offer an advantage in achieving improved nutritional status however, this improvement is not statistically significant. Morais et al [65] found serum nutritional markers and anthropometric parameters improved following the provision of implant retained overdentures. A randomised controlled trial testing for post treatment differences in nutritional status between patients with mandibular two implant retained overdentures and conventional complete dentures found significant improvements in anthropometric parameters for the implant, but not the conventional denture group, no significant differences between the two groups [99]. Another randomized controlled trial to compare food choices of edentulous adults provided with implant supported mandibular overdentures and conventional dentures found that although chewing difficulty and food choices improved in both groups, there were no significant differences between groups [67]. The authors of this study attributed this to participants not changing their food selection despite having an increased number of food choices available to them following treatment. They also suggested tailored dietary interventions may have altered the outcome.

Unsurprisingly, improving oral comfort and chewing ability for edentulous persons can result in improved nutritional status [55, 65, 99, 100]. Other studies have found food choices not to

improve following provision of new dentures [84, 101]. An improvement in dental status has been shown to improve objective functional ability. Improved function infers a wider range of healthy choices are available for selection. Although, prosthetic rehabilitation may improve function and chewing power, thus increasing food choices available, it may not be sufficient to alter behaviour [15].

Without tailored dietary advice, prosthetic rehabilitation alone does not result in satisfactory diet [66, 95, 97]. Nutritional counselling along with prosthetic rehabilitation has been found to improve nutrition [102]. For example, administering tailored nutritional information can increase fruit and vegetable consumption by 210g/d (equivalent to >2.5 servings). The provision of formal or informal help to those who have difficulty in purchasing, processing and eating food may improve nutrition levels [68].

1.4. Denture Satisfaction

Patients' interpretation of the difficulties they experience with their dentures is inherently personal and therefore highly subjective. Factors influencing denture satisfaction include patients receiving their preferred choice of treatment, personal expectations, prosthesis retention and stability, function, appearance, psychological factors and tailored dietary advice [103]. Patients' satisfaction may be more linked to their acceptance of denture limitations than the technical correctness of their dentures [15]. Generally, psychological and interpersonal factors seem to be important determinants of denture satisfaction and OHRQoL, perhaps more so than anatomic or clinical factors. Reported satisfaction with complete dentures ranges between 65 and 90% [104].

It is now generally agreed that patients' own evaluation of treatment success should form part of the overall evaluation of success along with traditional clinical measures. Inclusion of the patient's perspective allows for improvements in care and also supports the concept of patient-centred care. The clinician's assessment of a prosthesis does not reliably predict patient satisfaction [56]. Many edentulous persons have a strong preference for a treatment modality, which makes it difficult to measure a treatment effect without bias [105]. Bias often arises when participants in a study expect to receive implants but are placed in a control group and their response to treatment may be the result of disappointment with treatment allocation [106]. Alternatively, participants may elect not to enter a trial where treatment is randomised, which may reduce the general application of the results.

Satisfaction is highly dependent on initial expectations of treatment outcome. Many studies have reported that people seeking complete dentures are more likely to be satisfied with complete dentures than those seeking more advanced treatment (e.g. implants) who receive complete dentures [107].

Allen et al [95] conducted a prospective study involving three groups:

- (i) those who requested and received implants to stabilise a complete fixed or removable prosthesis,
- (ii) edentulous subjects who requested implant prostheses but received conventional dentures and
- (iii) those who requested and received conventional dentures.

This study found that although the participants in group (ii) reported an improvement in comfort of mandibular dentures which was statistically significant, overall these people were fairly dissatisfied with their treatment outcome. The authors felt it was possible that the

patients' dissatisfaction may have been influenced by the fact that they did not receive their preferred treatment. Patients who request implants would appear to have greater expectations of treatment. [108]

The delivery of tailored dietary advice to edentulous persons impacts their satisfaction with denture comfort, stability and chewing ability, depending on the nature of their prosthesis [109]. Authors of this study concluded this arose out of a re-evaluation of satisfaction when edentulous persons challenged themselves to consume more fruit, vegetables and fibre-rich foods. The implant overdenture group in this study had an increased level of satisfaction and perceived chewing ability while the complete denture group may have reawakened consciousness of the shortcomings of this prosthesis.

A study which specifically compared outcomes for maxillary and mandibular dentures found that stability and comfort distinguish maxillary denture acceptance from more generalized dissatisfaction with mandibular dentures. [110]

1.4.1. Denture Satisfaction Questionnaire

Variables were assessed on Category Scales (CAT) which were previously validated [111]. Individual variables assessed included general satisfaction, stability, retention, comfort, esthetics, ease of speaking and chewing. Participants were asked to choose a word which best described their responses to questions. This questionnaire has been validated in an Irish population [50].

Generally research on edentulism has considered all edentulous persons as a single group rather than looking at the various levels of anatomical complexity separately. To date, only one study has considered the relationship between classification of edentulism and denture satisfaction. None has looked at the association between diagnostic classification and either nutritional status or OHRQoL. Conventional complete dentures have been shown to improve OHRQoL and denture satisfaction previously. Their impact on nutritional status is less clear and the available evidence is conflicting. This study seeks to document the impact conventional complete dentures have on OHRQoL, nutritional status and denture satisfaction. As well as adding to the information currently available, this will also serve as baseline information for future planned research. Currently, collaborative research between the dental hospitals in Cork and Dublin seeks to investigate if participants who respond poorly to conventional treatment observe a greater improvement following provision of mandibular implant retained overdentures. No research has previously investigated if new conventional complete dentures offer a varying level of impact, according to diagnostic classification, regarding OHRQoL, nutritional status and denture satisfaction. This information offers the possibility of predicting successful treatment from baseline data. This would facilitate provision of more efficient treatment and selection of appropriate populations for implant treatment.

Chapter 2

Patients, materials and methods

2. Patients, materials and methods

2.1. Patient Recruitment

Potential participants were identified from the waiting lists of the Department of Restorative Dentistry and Periodontology at the Dublin Dental University and Hospital (DDUH) and general dental practices in the DDUH catchment area. Inclusion and exclusion criteria as outlined in *table 2.1* were applied.

Table 2.1: Inclusion and exclusion criteria

<u>Inclusion criteria:</u>	<u>Exclusion criteria:</u>
<ul style="list-style-type: none">• Edentulous patients who have previously had complete dentures made• Orthopantomograph already available	<ul style="list-style-type: none">• Patients who are edentulous for less than three months• No orthopantomograph available• Under 18 years of age• Adults with learning disabilities, terminal illness, mental illness or dementia.

A gatekeeper (Ms. Rose Glackin) was appointed to contact potential participants by mail inviting their participation. Ms. Glackin is a member of the DDUH administration staff and was involved in neither the research project nor service provision for the participants. This methodology ensured participants did not feel coerced into participation by a health care professional directly involved in their treatment. Potential participants were contacted by mail with the participant information leaflet (*Appendix I*), informed consent (*Appendix II*) and a letter to prospective participants (*Appendix III*) with a self addressed envelope enclosed and invited to contact the DDUH if they wished to participate. Potential participants were invited to discuss any queries about the study with the principal researcher whose contact details

were provided on the information leaflet. All participants signed a consent form (*Appendix II*) which was countersigned by the principal researcher once they were satisfied the participant was fully informed. Confidentiality was guaranteed.

2.2. Ethical Approval

Ethical approval was granted from the faculty of Health Sciences in Trinity College Dublin for this study.

Use of the following study forms was approved:

- Patient Participation Leaflet (*Appendix I*)
- Consent (*Appendix II*)
- Letter to prospective participants (*Appendix III*)
- American College of Prosthodontics - Prosthodontic Diagnostic Index - Classification of Edentulism (*Figure 2.1*)
- Oral Health Impact Profile – Edentulous (OHIP-EDENT) (*Table 2.2*)
- Mini Nutritional Assessment - Short Form (*Appendix IV*)
- Denture Satisfaction Questionnaire (*Figure 2.5*)

2.3. Data Collection and Storage

Participants were recruited for this study between September 2010 and April 2012. An identity number was generated for each participant allowing research data to be anonymised. This allows participants' personal information to be held in one document and all other information to remain anonymous. That one document holding participants' personal information is held in a locked cabinet in the Department of Restorative Dentistry and

Periodontology in the DDUH with access restricted to the principal investigator. All computerised data/information is also stored in a locked cabinet, again with restricted access and password secured. It has been duplicated on an independent external hard drive secured by a password known only to the investigator. The data/information that identify particular participants will be retained only for as long as may be needed for cross-reference during the study (i.e. until the work is fully reported and disseminated). It will be kept in a locked cabinet for five years after completion of the study.

Participation was voluntary and participants were free to withdraw from the study at any time. Any drop outs were documented and the reasons recorded where possible. These participants were fully documented up to the point of drop out.

2.4. Clinical Assessment

The clinical examination was carried out by the principal researcher (a qualified, insured dentist). This assessment was guided by the American College of Prosthodontists' checklist for classification of complete edentulism (*Figure 2.1*) [17]. The project supervisor had been trained thoroughly in the use of this checklist and from this gold standard, the principle researcher was calibrated. Under their guidelines a non-invasive, visual examination (with the aid of a mouth mirror) of the oral soft tissues and oral musculature was undertaken. In addition, the following parameters were recorded from clinical findings: muscle attachments, maxillomandibular relationships, conditions requiring preprosthetic surgery, limited interarch space, tongue anatomy and modifying factors (e.g. oral manifestations of systemic disease, psychosocial issues etc). Existing radiographs on the participant's record at the DDUH were

reviewed, if available, to facilitate recording of bone height in the mandible and maxilla. Radiographs were not prescribed as part of this assessment in consistence with the ALARA (as low as reasonably achievable) principle of radiation. The routine use of an orthopantomograph as a screening tool is no longer considered appropriate. Participant's weight (in kilograms) and standing height (in metres) were measured to allow calculation of their body mass index (BMI) as part of the nutritional assessment. Following completion, any necessary adjustments or repairs of the prostheses were carried out. Advice regarding oral and denture hygiene, as well as appropriate maintenance care, was given.

The participants completed the questionnaires (OHIP-EDENT, MNA-SF and DSQ) unassisted and were given the opportunity to clarify any of the questions they did not understand. Completion of the questionnaires took approximately 10-15 minutes and the clinical examination approximately 10 minutes.

2.4.1. American College of Prosthodontists' checklist for classification of complete edentulism

Checklist for Classification of Complete Edentulism				
	Class I	Class II	Class III	Class IV
Bone Height-Mandibular				
21 mm or greater				
16-20 mm				
11-15 mm				
10 mm or less				
Residual Ridge Morphology-Maxilla				
Type A-resists vertical & horizontal, hamular notch, no tori				
Type B-no buccal vest., poor hamular notch, no tori				
Type C-no ant vest, min support, mobile ant ridge				
Type D-no ant/post vest, tori, redundant tissue				
Muscle Attachments-Mandibular				
Type A-adequate attached mucosa				
Type B-no b attach mucosa (22-27), +mentalis m				
Type C-no ant b&l vest (22-27), +genio & mentalis m				
Type D-att mucosa in post only				
Type E-no att mucosa, cheek/lip moves tongue				
Maxillomandibular Relationships				
Class I				
Class II				
Class III				
Conditions Requiring Preprosthetic Surgery				
Minor soft tissue procedures				
Minor hard tissue procedures				
Implants - simple				
Implants with bone graft - complex				
Correction of dentofacial deformities				
Hard tissue augmentation				
Major soft tissue revisions				
Limited Interarch Space				
18-20 mm				
Surgical correction needed				
Tongue Anatomy				
Large (occludes interdental space)				
Hyperactive- with retracted position				
Modifiers				
Oral manifestation of systemic disease				
mild				
moderate				
severe				
Psychosocial				
moderate				
major				
TMD Symptoms				
Hx of paresthesia or dysesthesia				
Maxillofacial defects				
Ataxia				
Refractory Patient				
Guidelines for use of the worksheet				
1. Any single criterion of a more complex class places the patient into the more complex class.				
2. Initial preprosthetic treatment and/or adjunctive therapy can change the initial classification level.				
3. In the situation where the patient presents with an edentulous maxilla opposing a partially edentulous mandible, each arch is diagnosed with the appropriate classification system.				

Figure 2.1: American College of Prosthodontists' checklist for classification of complete edentulism

The Prosthodontic Diagnostic Index (PDI) of complete edentulism shown above in *Figure 2.1* [17] considers the following parameters to classify patients in one of four categories (Class I-IV):

- Mandibular Bone Height
- Maxillary Residual Ridge Morphology
- Mandibular Muscle Attachments
- Maxillomandibular Relations
- Conditions Requiring Pre-prosthetic Surgery
- Limited Interarch Space
- Tongue Anatomy
- Modifiers

Mandibular Bone Height

Mandibular bone height was measured in millimetres from an orthopantomograph of the participant if one was already available on the electronic dental record. Height was measured using a measuring tool on the electronic dental record. First the radiograph was calibrated by calculating the dots per inch (DPI) relative to the actual length of phosphor plate. This allowed the height of mandibular bone to be calculated. It is considered the most easily quantified and objective criterion for the mandibular edentulous ridge. It further provides an indication of the chronic debilitation associated with complete edentulism in the mandible. Resorption of the mandibular bone has sequelae for the following:

- a) denture bearing area,
- b) tissues remaining for reconstruction,
- c) facial muscle attachment/support,
- d) total facial height and
- e) ridge morphology.

Authors of the original paper describing this classification [17] suggested mandibular height be measured from the least vertical bone height of the mandible because they report this area is subject to the least amount of variation:

Type I (most favourable): residual bone height of 21mm or greater

Type II: residual bone height 16-20mm

Type III: residual bone height 11-15mm

Type IV: residual bone height of 10mm or less

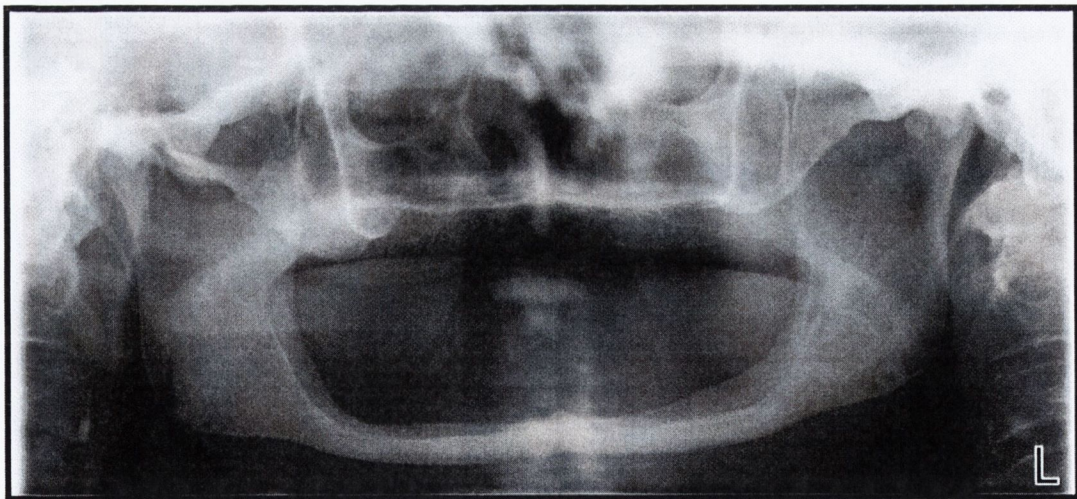


Figure 2.2: Type IV (residual bone height of 10mm or less)

Maxillary Residual ridge morphology:

This proves the most objective criterion for the maxilla, as measuring residual height is not reliable. Four types of ridge classification are presented.

Type A: the most favourable presentation of residual ridge morphology

- Vestibular depth is adequate in anterior labial and posterior buccal areas to best resist movement of the denture base in both the horizontal and vertical planes.
- Palatal morphology resists movement of the dentures base in both the horizontal and vertical planes
- Well defined tuberosities to resist vertical and horizontal movement of the denture base
- Well defined hamular notch establishing the posterior extension of the denture base
- No tori or bony exostoses

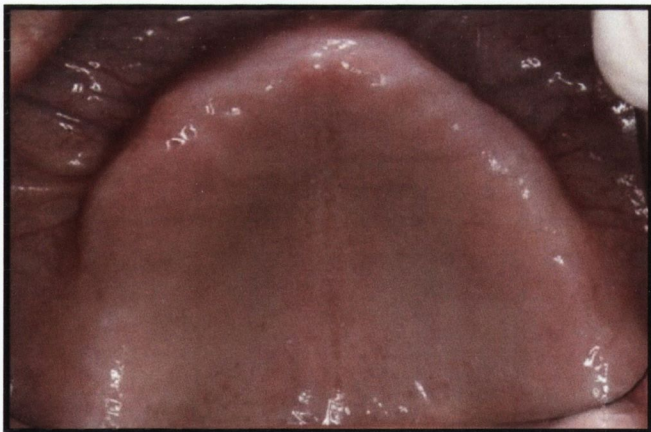


Figure 2.3: Type A maxillary residual ridge morphology

Type B

- Posterior buccal vestibule is reduced
- Palatal morphology resists vertical and horizontal movement of the denture base
- Hamular notches and tuberosities are poorly defined, compromising delineation of the posterior extension of the denture base
- Tori and/or lateral exostoses are rounded and do not affect the posterior extension of the denture base

Type C

- Loss of the labial vestibule anteriorly
- Palatal morphology offers little resistance to vertical and horizontal movement of the denture base
- Presence of maxillary palatal tori and/or lateral exostoses with bony undercuts which do not affect the posterior extension of the denture base
- Mobile anterior ridge with hyperplastic tissue offering minimum support and stability to the denture base
- Post malar space is reduced by the coronoid process during excursive movements

Type D

- Loss of anterior labial and posterior buccal vestibules
- Palatal morphology offers no resistance to vertical or horizontal movement of the denture base

- Palatal tori and/or lateral exostoses (rounded or undercut) which interfere with the posterior border of the denture
- Hyperplastic, flabby anterior ridge
- Prominent anterior nasal spine

Mandibular Muscle attachments:

The effects of muscular attachments and their location are more relevant to mandibular denture function.

Type A (most favourable)

- Attached mucosal base with muscle attachments not impinging on normal function

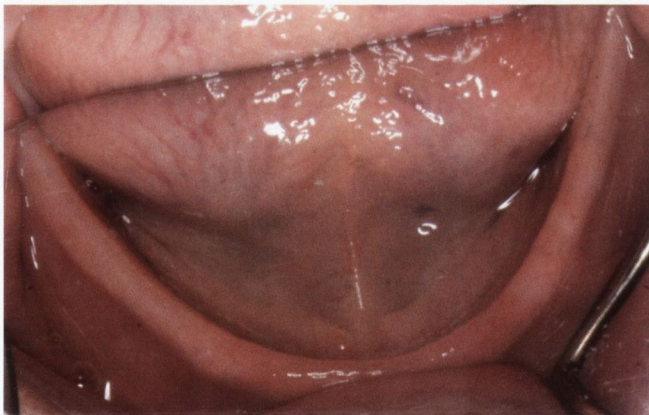


Figure 2.4: Type A mandibular muscle attachments

Type B

- Attached mucosal base in all regions except the labial vestibule
- Mentalis attaches near the crest of the ridge

Type C

- Attached mucosal base in all regions except buccal and lingual vestibules from canine to canine
- Genioglossus and mentalis attach near the crest of the alveolar ridge

Type D

- Only remaining site of attached tissue is in the posterior lingual region



Figure 2.5: Type D mandibular muscle attachments

Type E

- No attached mucosa

Maxillomandibular Relationship

This identifies the position of the artificial teeth in relation to the residual ridge and/or opposing dentition.

Class I (Most favourable)

- This relationship allows for tooth positioning with normal articulation of the teeth supported by the residual ridge

Class II

- Tooth positioning beyond normal ridge relation is required to attain esthetics, phonetics and articulation

Class III

- Tooth positioning beyond normal ridge relation is required to attain esthetics, phonetics and articulation (e.g. reverse horizontal overlap)

Conditions requiring pre-prosthetic surgery:

ACP-PDI class I and II are not indicated for pre-prosthetic surgery.

- Conditions indicating Class III anatomical complexity:
 - Minor soft tissue procedures
 - Minor hard tissue procedures
 - Implants – simple
- Conditions indicating Class IV anatomical complexity:
 - Implants with bone grafting – complex
 - Correction of dentofacial deformities
 - Hard tissue augmentation
 - Major soft tissue revisions

Limited Interarch Space

- Class III
 - 18-20mm interarch space
- Class IV
 - Surgical correction required

Tongue Anatomy

- Class III
 - Large (occludes interarch space)
- Class IV
 - Hyperactive (with retracted position)

Modifiers

- Class II
- Mild oral manifestations of systemic disease (e.g. xerostomia)
- Class III
 - Moderate oral manifestations of systemic disease
 - Moderate psychosocial
 - Temporomandibular disorder symptoms
- Class IV
 - Severe oral manifestations of systemic disease (e.g. erosive lichen planus affecting the oral mucosa)
 - Major psychosocial
 - History of paresthesia or dysesthesia
 - Maxillofacial defects
 - Ataxia (e.g. Parkinson's disease)

- Refractory patient

2.4.2. Quality of Life

Oral Health Impact Profile-edentulous (OHIP-EDENT) is a 19 item subset of OHIP-49 developed by Allen and Locker for use with edentulous patients. [54] OHIP-EDENT has the same 7 domains as in OHIP-49 but is a 19 item subset of the original questionnaire including only statements relevant to an edentulous population (*Table 2.2*). As in OHIP-49, a 5 point likert scale is used with responses ranging from 1=never to 5=very often. [54], shows the breakdown of questions included in each domain.

Table 2.2: OHIP-EDENT questions by domain category

Domain 1 : Functional Limitation	1. Have you had any difficulty chewing foods because of problems with your teeth, mouth or dentures?
	2. Have you had food catching in your teeth or dentures?
	3. Have you felt that your dentures have not been fitting properly?
Domain 2 : Physical Pain	4. Have you had painful aching in your mouth?
	5. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
	6. Have you had sore spots in your mouth?
Domain 3 : Psychological Discomfort	7. Have you had uncomfortable dentures?
	8. Have you been worried by dental problems?
Domain 4 : Physical Disability	9. Have you been self conscious because of your teeth, mouth or dentures?
	10. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?
	11. Have you been unable to eat with your dentures because of problems with them?
Domain 5 : Psychologic Disability	12. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
	13. Have you been upset because of problems with your teeth, mouth or dentures?
Domain 6 : Social Disability	14. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
	15. Have you avoided going out because of problems with your teeth, mouth or dentures?
	16. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?
Domain 7 : Handicap	17. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
	18. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?
	19. Have your felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

2.4.3. Nutrition

The MNA is an effective tool with a reliable scale and clearly defined parameters for evaluating nutritional status and risk of under nutrition. [64, 70, 112-114] A short 6 item screening version (MNA-SF) which takes 4 minutes to complete has been developed and validated to facilitate a two step screening process to be administered in low risk populations but still maintaining the accuracy and validity of the full MNA. [77] The following six key parameters were identified in a reanalysis of the original data used to develop the original MNA: [64]

- (i) Food Intake (in the last three months – graded as no change, moderate or severe)
- (ii) Weight Loss (in the last three months – graded as >3kg, 1-3kg, unsure or no weight loss)

Although certain instances of weight loss may be appropriate in the overweight elderly, it may also be due to malnutrition. The MNA loses its sensitivity when the question regarding weight loss is removed so it should be included even when the weight loss is deliberate because the person is overweight.

- (iii) Mobility (chair/bed bound or able to go out)
- (iv) Psychological Stress/Acute Disease
- (v) Neuropsychological Problems (dementia, depression or psychological problems)
- (vi) Body Mass Index (graded as <19, 19-21, 21-23, >23)

Only two out of the six parameters assessed by the MNA-SF had the potential to change following complete denture provision. Therefore, it was decided not to administer the MNA-SF at the post denture follow up.

Using the MNA-SF scoring system, if a patient scores 12-14, they are considered to have a normal nutritional status, 8-11 indicates the patient may be at risk of malnutrition and 0-7 indicates the patient is malnourished. A MNA-SF screening score of <11 suggests risk of malnutrition and this is confirmed by completion of the full MNA questionnaire. Once a person has been identified as being at risk of malnutrition, appropriate investigations and intervention where needed should be undertaken. [70]

2.4.4. Denture Satisfaction

The denture satisfaction questionnaire used is a modified version of that used by Tang et al (*Figure 2.5*). [115] The denture satisfaction questionnaire used in this study was self administered. Subjects rate their dentures on a Likert scale (1=totally satisfied to 5=not at all satisfied)

DENTURE SATISFACTION QUESTIONNAIRE

Please tick one box only.

General Satisfaction:

In general are you satisfied with your lower denture?

Not satisfied Neither satisfied nor dissatisfied Fairly satisfied Very satisfied

Physical Function: Please tick one box only

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
-----------------	------------------	------------------------	------------------	----------------------	------------------

Are you satisfied with the performance of your lower denture when chewing?

--	--	--	--	--	--

Does your lower denture cause difficulties when speaking?

--	--	--	--	--	--

Does your lower denture stay in place during use?

--	--	--	--	--	--

Is your lower denture comfortable?

--	--	--	--	--	--

Please circle only one answer

Physical Function:

1 How do you rate the quality of meals after having worn your present lower denture?

Worse No change Better Much better

2 Is your choice of food limited by your ability to eat with your lower denture?

Not at all A little A lot

Psychosocial Function:

1 Do you refuse social invitations because of difficulties with your lower denture?

Often Occasionally Never

2 How often do you avoid speaking with someone else because of difficulties your lower denture?

Often Occasionally Never

3 Do you consider your lower denture to be;

A foreign body A part of yourself both.

4 How do you evaluate your self-confidence after wearing you present lower denture?

Worse No change Better Much better

General Health

How has your lower denture changed your life?

Worse No change Better Much better

Figure 2.6: Denture Satisfaction Questionnaire

The variables assessed for mandibular dentures were:

- General satisfaction
- Satisfaction compared to natural teeth
- Retention
- Stability
- Comfort
- Ability to speak
- Occlusion
- Appearance
- Ability to chew and swallow certain foods

2.5. Denture Fabrication

Undergraduate dental and clinical dental technician students, who had successfully completed a laboratory based competence fabricated the dentures.

2.6. Statistical Analysis

The patient generated responses were compiled as numeric data. All data was entered into an electronic database (excel spreadsheet) and STATA version 12 statistical package for Windows was used to analyse results. Values from each individual question were presented

as frequencies, means and standard deviations. Descriptive statistics were reported including the total number of participants, number of withdrawals and reasons for withdrawal from the study. Participant demographics were given (male female ratio, age range of participants with the mean age and standard deviation). Breakdown of participants, both before and after complete denture provision, according to anatomical classification was presented. Length of time participants had been edentulous at presentation and age of their current dentures at presentation was reported. Total OHIP-EDENT, DSQ and MNA-SF scores for the full group and by classification were calculated.

Statistical tests used to address each objective:

1. To consider whether there is a relationship between the dependent variable (classification) and the independent variables (OHIP-EDENT, MNA-SF and DSQ)

There were too few participants in each class using the ACP classification. To facilitate analysis, ACP classes I and II were regrouped to group 1 and classes III and IV combined to form group 2. Two mean comparison tests were then performed on the two new classification groupings. To explain variation in the dependent variable (ACP classification of edentulism) with respect to the independent variables (OHIP-EDENT, MNA-SF and DSQ) a logistic regression analysis was conducted.

An ordinary least squares (OLS) regression was not feasible because of the nature of the dependent variable. Due to a small sample size, classification has been recoded to range from 0 to 1 to allow for a logistic regression. ACP classification levels which were originally I and II were re-coded as 1 and III and IV re-named as 0, thereby creating a binary dependent

variable suitable for a binomial logistic regression. A logistic regression model was run, including all OHIP-EDENT and DSQ questions initially. This identified a problem of collinearity amongst many of the questions from both questionnaires. This commonly arises when many of the questions relate to a common theme as was the case here. To overcome this difficulty a principle component analysis (PCA) was used. A PCA derives weighted linear combinations (OHIP-EDENT factors 1-3 and DSQ factors 1-4) of the original scores (OHIP-EDENT questions 1-19 and DSQ questions 1-12). These components contain roughly 70-80% of the total information in the original 19 OHIP-EDENT questions and 12 DSQ questions. Three components for OHIP-EDENT were identified and four components for DSQ, which significantly reduced the number of variables for the model and components were no longer correlated which allowed logistic regressions to be run. Logit models normally produce coefficients which are complex to interpret hence odds ratios and confidence levels were reported from a logistic regression of classification on the independent variables OHIP-EDENT, MNA-SF and DSQ scores.

2. To investigate if new dentures have an impact on OHIP-EDENT, MNA-SF and DSQ

Effect sizes and paired t-tests on the total group before and following provision of conventional complete dentures for

- OHIP-EDENT total,
- OHIP-EDENT domain totals,
- DSQ total,
- DSQ individual questions and
- MNA-SF total

3. To investigate if different classifications observe different changes in OHIP-EDENT, DSQ and nutrition following provision of new dentures

Independent t-tests for participants subdivided into 2 new classification groups (as described above) for the following parameters:

- OHIP-EDENT total
- OHIP-EDENT domain totals,
- DSQ total
- DSQ individual questions
- MNA-SF total

Effect sizes were calculated according to Cohen's criteria [36]: $((m1-m2)/sd1)$. An effect size of 0.2-0.5 was considered small, 0.5-0.8 was considered moderate and an effect size of 0.8 or higher was considered to be a large change. P values <0.05 were considered significant.

Chapter 3

Results

Results

3.1. Descriptive statistics

46 participants were recruited to the study, 14 men and 32 women with an age range of 49 to 91 years ($M=70.74$, $SD=10.15$). All 46 participants completed baseline questionnaires and a clinical examination. Subsequently, there were 3 drop outs; 1 participant died, 1 sought treatment elsewhere and 1 could not attend due to illness. 22 participants completed questionnaires 3 months after receiving new conventional complete dentures and were included in the second group. The flow of participants in the study is shown in *Figure 3.1* below. Age range for the second group was 53 to 91 years ($M=71.28$, $SD=10.54$) This group consisted of 15 females and 7 males. The breakdown of participants according to ACP classification for both groups is given in *Table 3.1*. Length of time participants had been edentulous on presentation ranged from 1 to 64 years ($M=28.58$, $SD=19.31$). Age of participants' dentures on presentation ranged from 1 to 60 years ($M=14.89$, $SD=15.86$). Length of time participants had been edentulous and age of participants' dentures on presentation was reported as frequencies and percentages in five year intervals and is given in *Tables 3.2* and *3.3* respectively. *Table 3.4* shows the frequency and percentages for the three grades of nutritional status. Mean values and standard deviations for the dependent variables (OHIP-EDENT total score, MNA-SF score and DSQ total score) both at presentation and following complete denture provision are given in *Table 3.5*. *Table 3.6* shows the mean scores for individual OHIP-EDENT questions both prior to and following provision of conventional complete dentures.

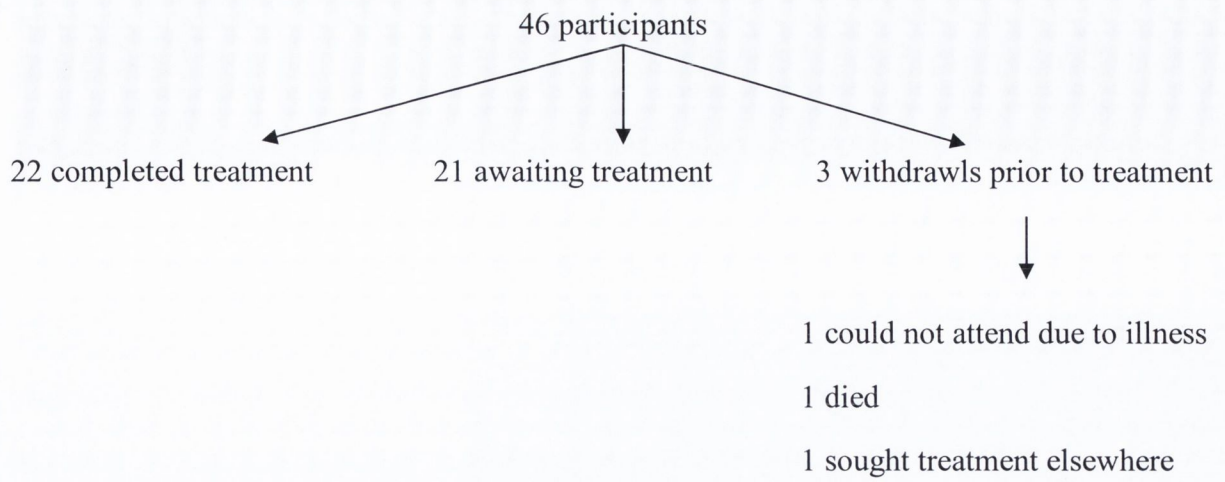


Figure 3.1: Flow of participants in the study.

Table 3.1: Number of participants according to ACP classification pre (n=46) and post (n=22) complete dentures

Classification (ACP)	Number of participants (PRE) n=46	Number of participants (POST) n=22
I	4	1
II	16	6
III	16	11
IV	10	4

Table 3.2: Frequency and percentages for length of time participants had been edentulous on presentation

Length of time edentulous	Frequency	Percentage
0-5	8	17
6-10	4	8
11-15	4	8
16-20	5	10
21-25	4	8
26-30	3	6
31-35	4	8
36-40	2	4
41-45	5	10
46-50	5	10
51-55	1	2
56-60	1	2

Table 3.3: Frequency and percentages for age of complete dentures at presentation

Age of complete dentures at presentation	Frequency	Percentage
0-5	16	35
6-10	10	22
11-15	4	9
16-20	7	15
21-25	1	2
26-30	1	2
31-35	1	2
36-40	2	4
41-45	1	2
46-50	2	4
51-55	1	2

Table 3.4: Frequency and percentages for the three grades of nutritional status.

Nutritional Status	Frequency	Percentage
Malnourished (0-7)	0	0
At risk of malnutrition (8-11)	11	23.91
Normal Nutrition (12-14)	35	76.09

Table 3.5: Mean values with standard deviations for OHIP-EDENT total score, MNA-SF score and DSQ total score at baseline (n=46) and following complete denture provision (n=22)

	Mean +/- standard deviation values at presentation (n=46)	Mean +/- standard deviation values following complete dentures (n=22)
OHIP-EDENT total score	49.30 +/- 21.14	38.09 +/- 13.06
MNA-SF score	12.48 +/- 1.85	13.59 +/- 0.85
DSQ total score	28.32 +/- 8.32	34.55 +/- 7.37

Table 3.6: Mean scores with standard deviations for OHIP-EDENT questions pre (n=46) and post (n=22) conventional complete dentures

OHIP-EDENT Question	Mean Score +/- standard deviation (Pre) n=46	Mean Score +/- standard deviation (Post) n=22
1	3.41 +/- 1.41	3.00 +/- 1.60
2	3.34 +/- 1.42	3.14 +/- 1.36
3	3.67 +/- 1.47	2.50 +/- 1.57
4	2.13 +/- 1.36	2.04 +/- 1.32
5	3.22 +/- 1.56	2.95 +/- 1.32
6	3.02 +/- 1.49	2.22 +/- 1.38
7	3.37 +/- 1.69	2.81 +/- 1.33
8	2.10 +/- 1.50	1.77 +/- 1.34
9	2.61 +/- 1.49	1.63 +/- 0.95
10	3.13 +/- 1.56	2.95 +/- 1.43
11	2.59 +/- 1.77	2.68 +/- 1.46
12	2.71 +/- 1.72	2.41 +/- 1.33
13	2.59 +/- 1.51	1.63 +/- 1.13
14	2.26 +/- 1.57	1.09 +/- 0.43
15	1.56 +/- 1.07	1.00 +/- 0.00
16	1.60 +/- 1.22	1.00 +/- 0.00
17	1.86 +/- 1.24	1.04 +/- 0.22
18	1.91 +/- 1.41	1.09 +/- 0.43
19	2.17 +/- 1.52	1.09 +/- 0.43

A qnorm plot which plots the quantiles of OHIP-EDENT total score (*Figure 3.2*) and DSQ total score (*Figure 3.3*) against quantiles of the normal distribution (Q-Q plot) to assess normality of the data are shown below. A line of best fit indicates the data are normally distributed for both. As is the convention with these data, parametric tests were used (two

group mean comparison tests, paired t-tests and independent t-tests). *Figure 3.4* shows a histogram for total nutrition score at baseline. The data are not normally distributed therefore non parametric tests (Wilcoxon signed rank test and Mann Whitney U-test) were used for these data.

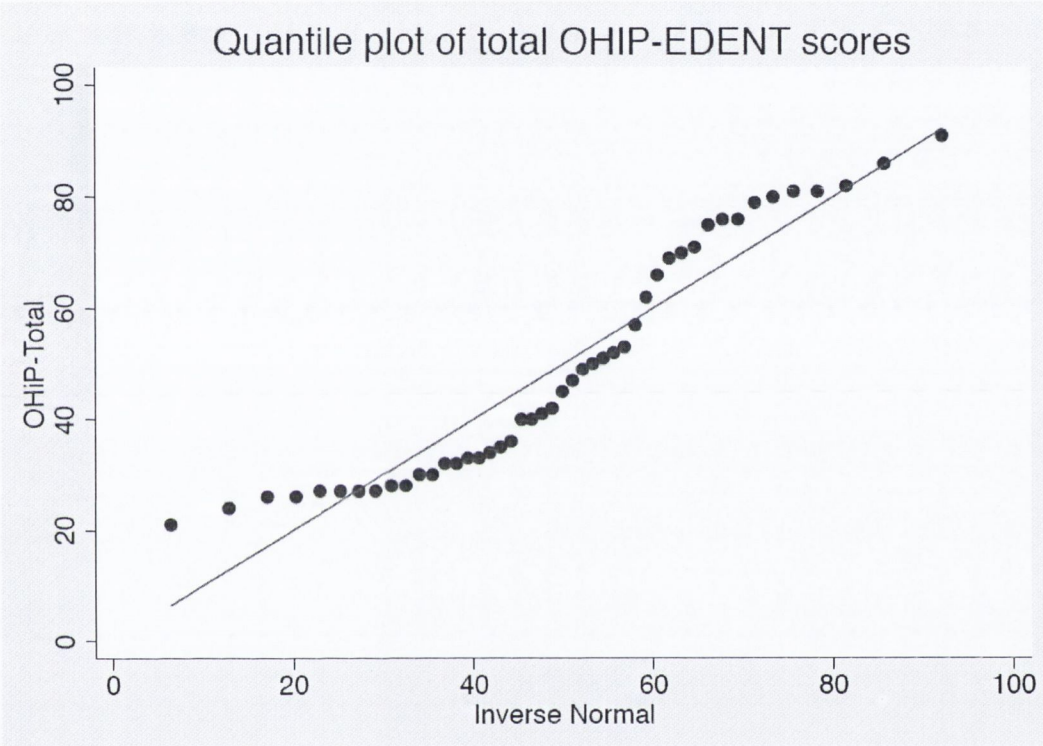


Figure 3.2: Quantile plot of total OHIP-EDENT scores (n=46)

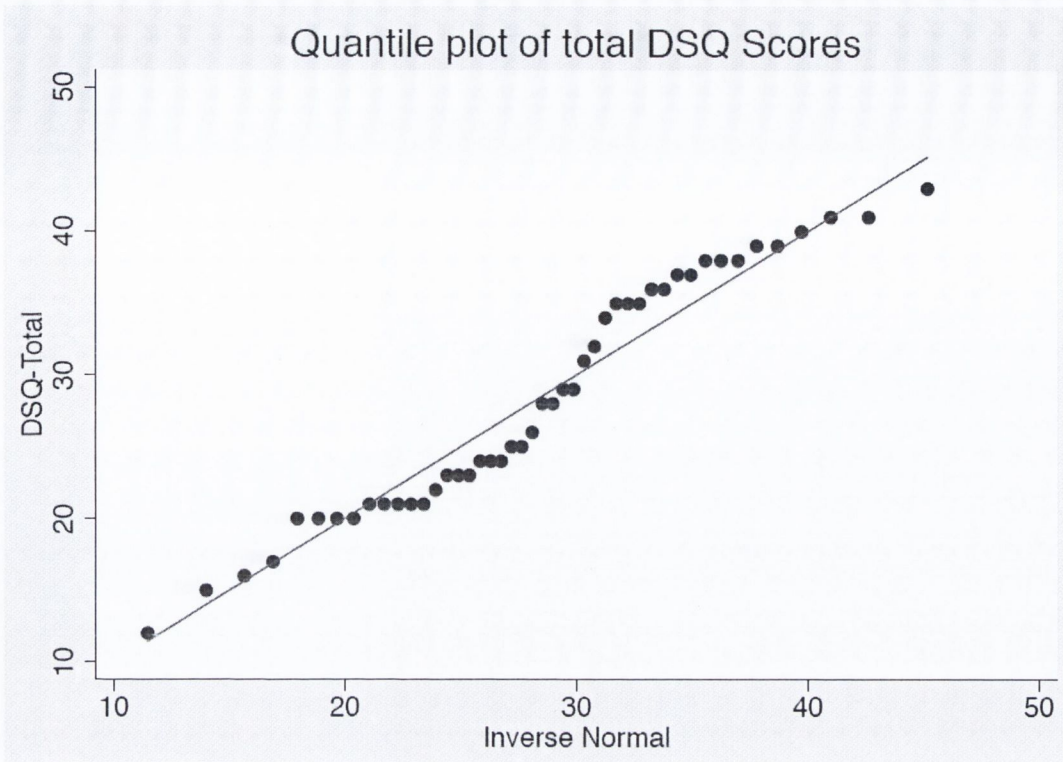


Figure 3.3: Quantile plot of total DSQ scores (n=46)

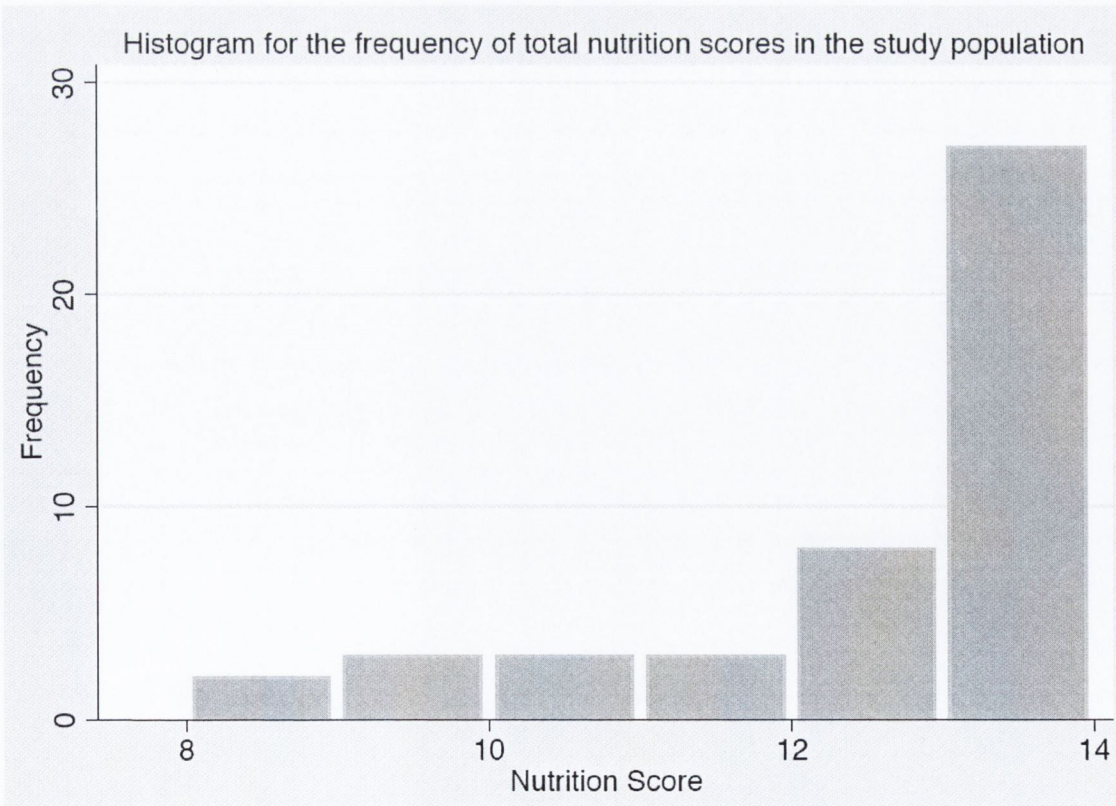


Figure 3.4: Histogram for the frequency of total nutrition scores in the study population (n=46)

3.2. Complexity of diagnosis in relation to

3.2.1. OHIP-EDENT

Participants for each ACP classification were too few to allow statistical analysis of all four classes individually. Instead ACP class I and II were combined to form group 1 and class III and IV regrouped together to form group 2. Mean scores and standard deviations, according to this new classification system, for OHIP-EDENT individual domains as well as total OHIP-EDENT score are given in *Table 3.7*. This table also gives p-values from the two group mean comparison tests. For the following analysis the conventional 0.05 significance level has been chosen as the critical value.

Table 3.7: Means and standard deviations for total OHIP-EDENT and domain scores according to new classification groups at baseline along with p-values from two group mean comparison tests

Parameter	Domain	Mean score and standard deviation for new group 1 (n=20) classification	Mean score and standard deviation for new group 2 (n=26) classification	p-values
OHIP-EDENT total		48.57 +/- 20.12	50.25 +/- 22.90	0.39
OHIP-EDENT Domain 1	Functional Limitation	10.42 +/- 3.60	10.45 +/- 3.67	0.49
OHIP-EDENT Domain 2	Physical Pain	11.92 +/- 4.90	10.9 +/- 5.29	0.75
OHIP-EDENT Domain 3	Psychological Discomfort	4.80 +/- 2.53	4.75 +/- 2.65	0.52
OHIP-EDENT Domain 4	Physical Disability	7.92 +/- 4.59	9.2 +/- 4.65	0.18
OHIP-EDENT Domain 5	Psychologic Disability	4.84 +/- 2.76	4.85 +/- 3.01	0.49
OHIP-EDENT Domain 6	Social Disability	4.53 +/- 2.30	5.7 +/- 3.88	0.11
OHIP-EDENT Domain 7	Handicap	3.96 +/- 2.61	4.25 +/- 3.02	0.37

3.2. MNA-SF

Two group mean comparison tests for MNA-SF total scores were conducted to compare groups 1 (n=20) and 2 (n=26). No statistically significant difference was found for MNA-SF total scores (group 1 mean = 12.46 +/-1.96 and group 2 mean = 12.5 +/- 1.73) between groups 1 and 2 (p=0.5274).

3.2.3. DSQ

Mean scores, according to this new classification system, for individual DSQ questions as well as total DSQ score are given in *Table 3.8*. These two new classes were then compared using two group mean comparison tests, p-values are also shown in *Table 3.8*. For the following analysis the conventional 0.05 significance level has been chosen as the critical value. There were no significant differences between groups 1 and 2 for individual DSQ questions and total score (p=0.1247) except for DSQ 1 which asked “In general are you satisfied with your lower denture?”

Table 3.8: Means and standard deviations for total DSQ and individual DSQ scores according to new classification groups at baseline along with p-values from two group mean comparison tests

	Mean score for new group 1 (n=20) classification	Mean score for new group 2 (n=26) classification	p-values
DSQ 1	2.19 +/- 1.26	1.60 +/- 0.94	0.04
DSQ 2	3.15 +/- 2.09	2.60 +/- 1.76	0.17
DSQ 3	2.27 +/- 1.92	2.60 +/- 1.95	0.72
DSQ 4	3.50 +/- 2.28	2.70 +/- 1.80	0.10
DSQ 5	3.53 +/- 2.23	3.10 +/- 1.89	0.24
DSQ 6	1.62 +/- 0.57	1.55 +/- 0.51	0.34
DSQ 7	2.23 +/- 0.86	2.00 +/- 0.72	0.17
DSQ 8	2.65 +/- 0.62	2.65 +/- 0.67	0.49
DSQ 9	2.73 +/- 0.53	2.60 +/- 0.68	0.23
DSQ 10	1.85 +/- 0.97	1.85 +/- 0.93	0.50
DSQ 11	1.92 +/- 0.68	1.75 +/- 0.55	0.18
DSQ 12	1.92 +/- 0.63	1.70 +/- 0.73	0.13
DSQ total	29.57 +/- 8.56	26.7 +/- 7.90	0.12

Table 3.9: Logistic regression for baseline data, using principle component analysis to identify the main factors that differ between groups 1 (n=20) and 2 (n=26)

Classification	Odds Ratio	P> t 	95% Confidence Interval (range)
OHIP-EDENT Factor 1	0.972	0.88	0.682 - 1.387
OHIP-EDENT Factor 2	1.925	0.10	0.882 - 4.200
OHIP-EDENT Factor 3	0.651	0.18	0.347 - 1.222
DSQ Factor 1	0.825	0.42	0.517 - 1.318
DSQ Factor 2	1.455	0.28	0.734 - 2.882
DSQ Factor 3	0.959	0.91	0.467 - 1.972
DSQ Factor 4	0.746	0.46	0.346 - 1.610
Nutrition Score	1.140	0.51	0.772 - 1.685

These results are suggestive although it is appreciated that none of the factors are statistically significant. Typically ORs in excess of 2 or 3 are considered to be clinically informative however results hovered around 1 in this study.

3.3. To identify whether new conventional complete dentures have an impact on

Paired t-tests were used to determine if there was a statistically significant difference between pre and post scores for the dependent variables following complete denture provision. Paired t-tests can be used on paired data before and after an intervention. Paired t-tests challenge the null hypothesis that the difference between two responses, measured on the same statistical unit, have a mean value of zero. Effect sizes were used to determine the magnitude of the effect of the intervention clinically.

3.3.1. OHIP-EDENT

A reduction in OHIP-EDENT score following provision of conventional complete dentures indicates an improvement in OHRQoL (mean score pre 47.27 +/- 22.20, mean score post 38.09 +/- 21.14 for paired data, n=22). A t-test found a statistically significant improvement in OHRQoL as indicated by $p=0.0246$ for OHIP-EDENT total score. OHIP-EDENT summary scores are shown in box plot format below (*Figure 3.5*). The range for OHIP-EDENT total scores was much smaller following complete denture provision. P-values for OHIP-EDENT total score at a domain level are given in *Table 3.8*. Statistically significant differences indicated by p-values <0.05 (shown in bold) were seen for all domains except physical pain and physical disability. Effect sizes for the same data are shown in *Table 3.9*. Cohen [116] has quantified effect sizes likely to be clinically meaningful as 0.2 = small, < 0.6 moderate and > 0.8 large.

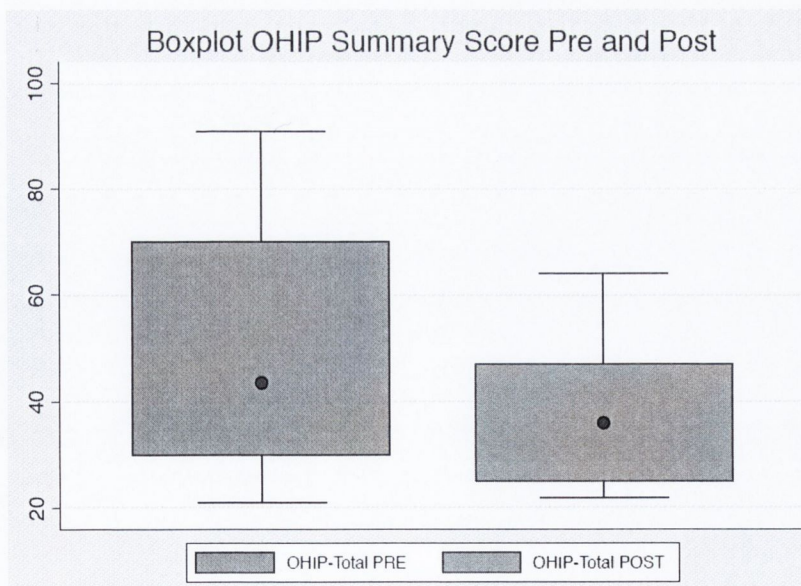


Figure 3.5: Boxplot OHIP-edent summary score pre and post conventional complete dentures (n=22)

No large effect sizes were observed but medium effect sizes were seen for the same domains which showed statistically significant differences. A medium effect size for OHIP-EDENT total was observed (0.53).

Table 3.10: Paired t-tests (p-values) for OHIP-EDENT total domain score

Domain		Paired t-tests Before and after complete denture provision, n=22 (P-values)
Domain 1	Functional Limitation	0.0685
Domain 2	Physical Pain	0.2452
Domain 3	Psychological Discomfort	0.0083
Domain 4	Physical Disability	0.5000
Domain 5	Psychologic Disability	0.0014
Domain 6	Social Disability	0.0019
Domain 7	Handicap	0.0022

*Values in bold indicate statistical significance < 0.05

Table 3.11: Effect sizes for OHIP-EDENT total domain score

Domain		Effect Size* Before and after complete denture provision (n=22)	Level of change
Domain 1	Functional Limitation	0.500	Medium
Domain 2	Physical Pain	0.283	Small
Domain 3	Psychological Discomfort	0.537	Medium
Domain 4	Physical Disability	0.093	Small
Domain 5	Psychologic Disability	0.745	Medium
Domain 6	Social Disability	0.643	Medium
Domain 7	Handicap	0.687	medium

* effect size = (M1-M2)/SD

3.3.2. DSQ

An increase in DSQ score following provision of conventional complete dentures indicates an improvement in denture satisfaction levels (mean score pre 28.95 +/- 8.06, mean score post 34.54 +/- 7.37 for paired data, n=22). A small p-value of 0.0015 suggests that we can reject the null hypothesis that new conventional complete dentures have no impact on denture satisfaction (total DSQ score) at the significance level of 0.05. This is reflected in a moderate effect size of -0.7 observed for DSQ total. Summary DSQ score pre and post is illustrated in box plot format in *Figure 3.6* below. The median for DSQ total following complete denture provision is greater and generally there are higher DSQ scores overall in the post group. A statistically significant difference is seen for the majority of DSQ individual questions as shown in *Table 3.10* below. This is further reflected in the effect sizes (*Table 3.11*), the majority of which showed moderate change while a large effect size was observed for the

question “How do you rate the quality of meals after having worn your present lower denture?” Worthy of note is that a negative sign for effect sizes does not indicate a negative effect, as it is the magnitude rather than the direction of the effect which is of interest.

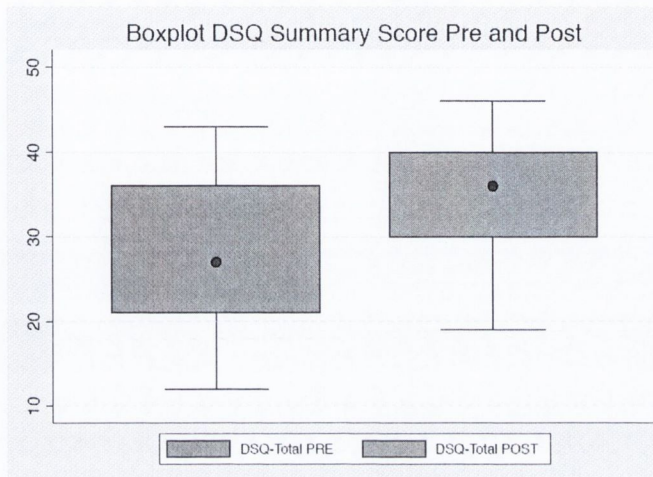


Figure 3.6 Boxplot DSQ summary score pre and post conventional complete dentures (n=22)

Table 3.12: Paired t-tests (p-values) for each DSQ question

	DSQ Question	Paired t-tests Before and after complete denture provision, n=22 (p-value)
1	In general are you satisfied with your lower denture?	0.0038
2	Are you satisfied with the performance of your lower denture when chewing?	0.0077
3	Does your lower denture cause difficulties when speaking?	0.8186
4	Does your lower denture stay in place during use?	0.0094
5	Is your lower denture comfortable?	0.2380
6	How do you rate the quality of meals after having worn your present lower denture?	0.0024
7	Is your choice of food limited by your ability to eat with your lower denture?	0.4234
8	Do you refuse social invitations because of difficulties with your lower denture?	0.0079
9	How often do you avoid speaking with someone else because of difficulties your lower denture?	0.0518
10	Do you consider your lower denture to be; a foreign body, a part of yourself or both?	0.3326
11	How do you evaluate your self-confidence after wearing your present lower denture?	0.0144
12	How has your lower denture changed your life?	0.0286

*Values in bold indicate statistical significance <0.05

Table 3.13: Effect sizes for each DSQ question (n=22)

	DSQ Question	Effect sizes* Before and after complete denture provision	Level of change
1	In general are you satisfied with your lower denture?	-0.7	Medium
2	Are you satisfied with the performance of your lower denture when chewing?	-0.5	Medium
3	Does your lower denture cause difficulties when speaking?	0.2	Small
4	Does your lower denture stay in place during use?	-0.7	Medium
5	Is your lower denture comfortable?	-0.3	Medium
6	How do you rate the quality of meals after having worn your present lower denture?	-1.1	Large
7	Is your choice of food limited by your ability to eat with your lower denture?	-0.1	Small
8	Do you refuse social invitations because of difficulties with your lower denture?	-0.5	Medium
9	How often do you avoid speaking with someone else because of difficulties your lower denture?	-0.4	Medium
10	Do you consider your lower denture to be; a foreign body, a part of yourself or both?	-0.2	Small
11	How do you evaluate your self-confidence after wearing your present lower denture?	-0.6	Medium
12	How has your lower denture changed your life?	-0.5	Medium

* effect size = (M1-M2)/SD

large effect sizes are indicated in bold

3.4. To investigate if different classifications observe different changes in the following after provision of new dentures

As for the previous logistic regression model, the diagnostic classification groups were recoded as 1 and 0 and a PCA run to identify the most important underlying factors from both OHIP-EDENT and DSQ questionnaires. The logistic regression results from post complete denture provision are shown in *Table 3.16*.

Table 3.14: Logistic Regression comparing group 1 and 2 following complete denture provision (n=22)

Classification	Odds Ratio	P> t 	95% Confidence Interval (range)
OHIP-Factor 1	0.956	0.98	0.015 - 60.473
OHIP-Factor 2	77.055	0.46	0.001 - 7,000,015.696
OHIP-Factor 3	1.550	0.81	0.047 - 51.484
DSQ-Factor 1	0.255	0.35	0.014 - 4.509
DSQ-Factor 2	0.016	0.48	0.000 - 1,687.926
DSQ-Factor 3	22.658	0.39	0.019 - 26,507.412
DSQ-Factor 4	0.099	0.60	0.000 - 542.872

None of the factors from the logistic regression analysis was statistically significant. Improvement in OHRQoL and denture satisfaction for groups 1 and 2 following complete denture provision were compared. At an initial glance, odds ratios for OHIP factor 2 and DSQ Factor 3 would appear highly significant. Typically odds ratios greater than 2 or 3 are considered clinically informative however the range of confidence intervals observed here is so wide, that the odds ratios become meaningless.

3.4.1. OHIP-EDENT

As previously, the original four ACP classification levels were regrouped into two new groups combining ACP class I and II to form group 1 and ACP class III and IV to form group 2. The difference between pre and post scores was calculated for each of the three dependent variables and independent t-tests performed to see if there was any difference according to classification. There was no significant difference in the change in total OHIP-EDENT score observed for both levels of classification regrouped as described above (mean score for group 1 6.85 +/- 22.77, mean score for group 2 10.2 +/-20.13) (p-value = 0.3656). Similarly independent t-tests showed no significant differences in the change observed for both classification groups at a domain level (results in *Table 3.12*).

Table 3.15: Independent t-test (p-values) for OHIP-EDENT domains comparing groups 1 and 2 (n=22)

Domain		Independent t-test (P-value)
Domain 1	Functional Limitation	0.6429
Domain 2	Physical Pain	0.2913
Domain 3	Psychological Discomfort	0.4032
Domain 4	Physical Disability	0.3911
Domain 5	Psychologic Disability	0.2497
Domain 6	Social Disability	0.5087
Domain 7	Handicap	0.2070

3.4.2. DSQ

There was no significant difference between the two new classification groups' improvement in DSQ total scores following complete denture provision as indicated by an independent t-test (mean score for group 1 6.28 +/- 5.96, mean score for group 2 5.26 +/- 8.71) (p-value=0.3917).

Table 3.16: Independent t-test (p-values) for DSQ questions, comparing the results for groups 1 and 2 (n=22)

DSQ Question		Independent t-test (P value)
1	In general are you satisfied with your lower denture?	0.1295
2	Are you satisfied with the performance of your lower denture when chewing?	0.3125
3	Does your lower denture cause difficulties when speaking?	0.6766
4	Does your lower denture stay in place during use?	0.1888
5	Is your lower denture comfortable?	0.6841
6	How do you rate the quality of meals after having worn your present lower denture?	0.8246
7	Is your choice of food limited by your ability to eat with your lower denture?	0.7038
8	Do you refuse social invitations because of difficulties with your lower denture?	0.5701
9	How often do you avoid speaking with someone else because of difficulties your lower denture?	0.2599
10	Do you consider your lower denture to be; a foreign body, a part of yourself or both?	0.4344
11	How do you evaluate your self-confidence after wearing your present lower denture?	0.6299
12	How has your lower denture changed your life?	0.2228

Chapter 4

Discussion

4. Discussion

4.1. General Aspects

This study aimed to investigate if a diagnosis based on complexity of edentulism was related to patient reported outcomes and response to conventional complete denture treatment. Also it aimed to investigate if conventional complete dentures have an impact on OHRQoL, nutrition and denture satisfaction.

On average, participants had been edentulous for 28.58 years. The average age of the participants' existing dentures on presentation was 14.89 years. The length of time participants had been edentulous was comparable to other studies but age of the participants' existing dentures on presentation was higher than that reported elsewhere. Boerrigter et al [117] reported a mean edentulous period in the mandible of 23.2 years and 25.7 years in the maxilla with a mean age for mandibular dentures of 6.6 years and 6.9 years for maxillary dentures. Meijer et al [118] reported a mean edentulous period in the mandible of 21 years and 25.7 years in the maxilla with a mean age for mandibular dentures of 6.6 years and 6.9 years for maxillary dentures. Similarly, Geertman et al [119] reported an edentulous period in the mandible of 21 years, 25 years in the maxilla and age of maxillary and mandibular dentures 6 years on average. There is a lack of consensus regarding the longevity of complete dentures [120], a best estimate has been suggested to be between 5-8 years. Naturally, different levels of adaptation would be present in a group showing such a level of variation. No formal assessment of the quality of participants' dentures was made. It is conceivable that there was a wide variation in the quality given that the dentures had been made in a number of settings by multiple operators over a long period of time. No assessment of prosthetic

status, whether they were wearing denture(s), level of satisfaction with their denture(s), or adaptation was made.

Firstly, the distribution of the data was investigated to consider which tests (parametric or non-parametric) were most suitable to be used. A line of best fit on qnorm plots of the quantiles for the dependent variables against quantiles of the normal distribution (Q-Q plot) indicated the data follows close to a normal distribution for OHIP-EDENT and DSQ data sets. Hence parametric tests were used for this data (paired t-tests, two group mean comparison tests, independent t-tests). Nutritional scores did not follow a normal distribution and non parametric tests were used for this data (Wilcoxon signed rank and Mann-Whitney U tests). Whether to treat data arising from questionnaires using Likert scales and visual analogue scales as parametric or non-parametric has been the subject of much debate. This is because responses do not follow a linear format e.g. a response of “never” is scored as “1” while “very often” is scored as “5” but this does not infer that a response of “very often” is five times better than responding “never”. Generally studies dealing with Likert scale based questionnaires have used parametric statistical tests for data sets showing a normal distribution [15, 56, 121].

There were too few participants in each class when using four classes of the ACP classification. For the purposes of analysis, ACP classes I and II were regrouped to form group 1 and classes III and IV regrouped to form group 2. No significant differences were found between both classification groups at baseline regarding OHIP-EDENT and DSQ total scores, regardless of whether parametric or non-parametric tests were used.

Previously validated and commonly used questionnaires were chosen for this study. Closed-ended questions make compilation and analysis of the data more straightforward. However, the use of semi-structured interviews can identify information which might be missed by using a questionnaire based approach which generates a forced response. These interviews are flexible, allowing new questions to be brought up during the interview as a result of the interviewee's responses. This approach was not used in this study but might be interesting for future work in this area. Interviewing skills are required for this approach with careful preparation to ensure questions are not prescriptive or leading. Appropriate skills are required to analyse the data which can be time consuming. Sufficient interviewees are required to allow general comparisons be made.

When using patient based outcome (PBO) measures, the fundamental aim is to detect differences between groups, either at a point in time or over time. Generally scores are aggregated and a test of statistical significance applied. Guidance is limited on what precisely constitutes clinical relevance. There are no set criteria for what constitutes mild, moderate or severe impact of oral disorders according to PBO score. A score is the cumulative effect of many individual responses. Persons may have the same score but have different individual difficulties making it impossible to profile a score. Jaeschke et al [122] defined minimally important difference (MID) as “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive cost, a change in the patient's management”. Effect sizes give clinically relevant differences. Cohen's equation has been used to calculate effect sizes $(M1-M2)/SD$. Effect sizes are used here for the benefits of comparison with existing research in this area.

4.2. If complexity of anatomical classification of edentulism relates to OHRQoL, nutrition or denture satisfaction.

Logistic regression looks at the size of the effect which the dependent variables have on the independent variable. As all of the questions for OHIP-EDENT and DSQ pertained to the same theme they demonstrated multi-colinearity in the logistic regression and a principle components analysis (PCA) was required to identify key underlying dimensions on which to run the logistic regression. PCAs are weighted linear combinations of the original scores and are selected based on eigenvalues. An eigenvalue represents the amount of variance accounted for by a given component.

To explain the variation in the dependent variable (ACP classification of edentulism) with respect to the independent variables (OHIP-EDENT, MNA-SF and DSQ) a logistic regression analysis was conducted. None of the results from the logistic regression have proven statistically significant. Further, two group mean comparison tests agree with these findings. No statistically significant findings were found, regarding OHRQoL for OHIP-EDENT total score as well as individual domains, nutritional status and for DSQ total score as well all individual DSQ questions, except DSQ 1, between different levels of anatomical classification. These findings are in agreement with previous work in this area (a study of 107 edentulous patients) which also failed to identify a relationship between ACP classification of edentulism and patients' self-reported satisfaction with their complete dentures [20]. Similarly, this study used the ACP classification of edentulism but the McGill satisfaction Visual Analogue Scale was used to assess denture satisfaction. The association between complexity of diagnosis of edentulism and OHRQoL and nutrition has not previously been reported in the literature.

Two group mean comparison tests found a statistically significant difference between group 1 and 2 regarding DSQ 1 which asked “In general are you satisfied with your lower denture?” This is an interesting finding as it would appear to be an apparent contradiction; total DSQ score reveals no statistical significance related to anatomical complexity, yet when the population is asked to report generally on their denture satisfaction, this shows statistical significance. Multidimensional measures are sometimes used to make a broad assessment and although it is a simple approach, they have been found to correlate with more complex measures [33]. Higher levels of denture satisfaction were found for the group 2, which is the regrouping of ACP classification levels III and IV (i.e. a greater level of anatomical debilitation).

4.3. To identify whether new conventional complete dentures have an impact on OHRQoL and denture satisfaction.

Many studies have reported previously that provision of new conventional complete dentures offer an improvement in OHRQoL [55, 60, 106] and denture satisfaction [106]. This is in agreement with the findings of this study. The effect of new dentures on nutritional status, despite being the subject of much research [65, 83, 94, 95], is less clear. There is some evidence to suggest food choices do not improve following provision of dentures [84, 101] while other research shows an improvement in nutritional status [55, 65, 99, 100]. While prosthetic rehabilitation may improve the individual’s capacity to eat healthy foods it does not imply the individual will make healthy food choices. Tailored dietary advice delivered alongside conventional dentures has been found to improve nutrition [66, 95, 97, 102]. This

approach was not taken in this study but could be an interesting adjunct in future research in this area.

An a priori power calculation was not possible as there was no available data on which to base the calculation. Limited statistical power, because of the modest sample size in the present study ($N = 46$), may have played a role in calculating the significance of some of the statistical comparisons conducted. A post hoc power analysis revealed that on the basis of the mean, between-groups comparison effect size observed in the present study ($d=0.530315$ for OHIP-EDENT total score, $d= -0.6024772$ for total MNA-SF score and $d= -0.7473884$ for total DSQ score), a sample of approximately 52, 35, 34 respectively would be needed to obtain statistical power at the recommended .80 level [116]. The figures required to detect statistical significance have not been met, in this current study, as the number of participants who completed treatment and post treatment questionnaires was 22.

According to the Likert scale used, an answer of “very often” which is scored as 5, indicates a negative response (“Have you had food catching in your teeth, mouth or dentures?”). Therefore a reduction in OHIP-EDENT score indicates an improvement in OHRQoL. *Figure 3.5* shows, using a boxplot format, that the range of OHIP-EDENT scores, total OHIP-EDENT scores and the median of OHIP-EDENT scores have reduced following provision of complete dentures. This indicates that the participants in this study experienced an improvement in OHRQoL following provision of complete dentures. The amount of change was quantified by a medium effect size and results of a t-test indicated a statistically significant improvement. This is a greater level of change than observed in the original article describing the OHIP-EDENT modified version of OHIP for edentulous subjects [54].

That original article reported a small effect size (0.4) following conventional complete denture treatment. Their mean OHIP-EDENT total score following treatment was 23.1 compared with 19.09 in this study (the scale used has been adjusted to run from 0-4 for comparison with this previous study). Their effect size for denture satisfaction was large (1.4) compared with a moderate effect size observed here (0.7). Previous results from a randomized controlled trial comparing implant-retained mandibular overdentures and conventional dentures also agree with these findings [106]. A significant improvement in OHRQoL following both types of treatment ($p < 0.001$) was found by Allen et al. This study used OHIP-49 rather than OHIP-EDENT as used here. Here, at a domain level, statistically significant improvements were observed for all domains except physical pain and physical disability and effect sizes computed a medium level of change relevant clinically for these domains. This echoes findings from a previous study which also reported a significant improvement in OHRQoL, following the provision of new conventional complete dentures, for 4 of the 7 domains ; psychological discomfort and disability, social disability and handicap (as measured with OHIP-EDENT) [123].

There are three possible outcomes for the MNA-SF namely; adequate nutrition (12-14), at risk of malnutrition (8-11) and malnourished (0-7). An increase in MNA-SF score indicates an improvement in nutritional status. In this study, a statistically significant improvement in nutrition was observed. However, both prior to and following provision of conventional complete dentures, the average nutritional status was categorised as “adequate nutrition” so whether the patient has benefited from any real improvement in nutritional status questionable. Further, only two out of six aspects investigated by the MNA-SF were likely to potentially change following provision of new conventional complete dentures. These aspects were “Has food intake declined over the past 3 months due to loss of appetite, digestive

problems, chewing or swallowing difficulties” and “Weight loss during the last 3 months”. Therefore, it is highly unlikely that the MNA-SF would have had the potential to accurately detect any change in nutritional status which can be solely attributed to improved conventional complete dentures. Nutrition is complex and influenced by more factors than masticatory ability and oral health alone. Edentulism is associated with lower socioeconomic status and lower education amongst other factors. Hence edentulism and malnutrition have common risk factors though a cause-effect relationship has not been reported in the literature. An improvement in prosthetic status has been shown to increase chewing capacity and function which increases food choices available but does not always result in an improvement in nutritional status. Dietary education along with provision of a new prosthesis has been shown to improve nutrition. Although there is strong evidence that tooth loss is associated with poor food intake and people with tooth loss also exhibit compromised nutrition, they are generally cross sectional studies. Thus, one must be judicious in attributing the changes in nutrition to a cause and effect relationship [124]. This is an interesting area for further qualitative research.

Responses to the DSQ were based on a Likert scale where an answer of “all the time” which is scored as 5 indicates a positive response (“Are you satisfied with the performance of your denture when chewing?”). An increase in DSQ score indicates an improvement in denture satisfaction. Mean total DSQ scores for all participants increased following provision of conventional complete dentures, indicating an improvement in overall denture satisfaction. This improvement was found to be statistically significant and was quantified as a moderate effect size. This finding agrees with previous work in this area from Allen et al [106] who reported a statistically significant improvement in denture satisfaction levels following the provision of conventional complete dentures ($p < 0.001$). For individual questions, statistically

significant improvements were observed for the majority of questions (8 out of 12). Effect sizes computed a medium level of change relevant clinically for these questions. One question “How do you rate the quality of meals after having worn your present lower denture?” had a large effect size (-1.18). This finding is interesting given a statistically significant improvement in nutrition was also observed in this population and also that only a small effect size was observed for the DSQ question asking “Is your choice of food limited by your ability to eat with your lower denture?” A recent randomised clinical trial found a high level of association between edentate patients’ (n=255) denture satisfaction and OHRQoL [125]. More specifically chewing ability and oral condition were the elements of denture satisfaction most associated with OHRQoL, predicting 46.4% of its improvement following treatment.

4.4 To investigate if different classifications observe different changes for the dependent variables after provision of new dentures

All dependent variables (OHIP-EDENT, MNA-SF and DSQ) improved following provision of conventional complete dentures. Analysis then moved to whether participants with varying levels of anatomical complexity improved to varying levels. As previously, data was divided into two groups of anatomical complexity as there were too few participants to perform robust analysis on all four classes of ACP classification.

Improvement in OHRQoL, nutrition and denture satisfaction for groups 1 and 2 following complete denture provision were compared with logistic regression analysis. None of the factors was statistically significant. No statistically significant improvement in OHRQoL (both for OHIP-EDENT total score and at domain level) between the two groups of

anatomical complexity was found following complete denture provision. No significant difference was observed between different groups of classification in nutritional terms following the provision of new complete dentures. Again, this finding does not come as a surprise given the high initial percentage of participants who were classified as having adequate nutrition (75%). These participants could not improve nutritional status category as classified by MNA-SF. DSQ total score and individual questions did not observe a statistically significant difference between both groups of anatomical complexity following provision of complete dentures. The association between diagnostic classification of edentulism and improvement in OHRQoL, nutrition and denture satisfaction has not previously been reported in the literature.

5. Limitations

There were no previous studies recording sufficiently similar data to that for this study which precluded the use of an a priori power calculation. The population sample was a convenience sample. Whether this sample can be assumed to represent the general population at large is unknown and a limitation of this study. It is however likely that these participants were more representative of the general population than would previously have been seen in a dental hospital setting. This is because of Health Service Executive cutbacks implemented over the course of this study. Routine funding of complete dentures was withdrawn from the General Medical Scheme which it can be assumed had the effect of more referrals being made to the hospital service. This means it was no longer just cases beyond the scope of general dental practitioners which were being referred to the DDUH. This may account for the reasonably good spread of anatomical complexity seen amongst the participants.

All clinical appointments for fabrication of complete dentures were conducted by undergraduate clinicians. Timely fabrication of dentures for the participants was constrained by the availability of undergraduate dental and clinical dental technician students, who had successfully completed a laboratory based competence, to provide treatment. This accounts for the smaller post treatment group. Although treatment was completed by multiple operators, which introduced inter-operator variability, procedures were standardised and all operators had received standard training in principles of complete denture fabrication. All treatment was carried out under the supervision of a qualified dentist.

The overall sample size was small and further reduced in the post intervention group. Thus the distribution of participants with different classifications of edentulism was poor with only a single participant with class I anatomical complexity in the post-treatment group. This issue

was circumvented by regrouping ACP classifications 1 and 2 together and 3 and 4 together to make two new classification subsets.

The introductory article on the ACP classification system [17] acknowledges that measuring mandibular bone height radiographically is not completely repeatable. It is susceptible to variation in radiographic technique, patient positioning and image magnification from varying panoramic machines. They recommend taking the measurement from the radiograph in the anterior mandibular region at the portion of the least vertical height which they report to be the area of least variation between radiographs.

The MNA-SF has demonstrated good sensitivity and specificity when detecting those who are both malnourished and at risk of malnutrition. As the majority of participants in this study were found to be adequately nourished at baseline, it is difficult to say whether any improvement in MNA-SF score represented any real improvement in nutritional status. Further only two out of six items investigated by MNA-SF pertained to factors which had the potential to improve following dental intervention (“Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?” and “Weight loss during the last 3 months”).

6. Future Studies and Suggestions

Qualitative interviews can generate more in depth information on a topic than can be found from questionnaires alone. The association between ACP classification of edentulism and OHRQoL and nutrition has not previously been reported, further study (with a population size based on power calculation reported here) would be interesting to confirm results observed here.

An alternative measure of nutritional status could offer more information on any changes in nutrition following prosthetic intervention.

Plans are underway with the Dublin Dental University and Hospital in collaboration with the Cork Dental Hospital to continue on work in this area. The overall aim of this project is to develop a predictive model for the treatment of edentulous patients. One strand will add to the database established for this study. Semi-structured interviews will be used to collect data. Themes identified from these interviews will be used to determine the content validity of currently used health status measures for quantitative assessment. Participants who are not satisfied following conventional denture therapy will be invited to have a two implant retained mandibular overdenture provided. Subsequently their denture satisfaction and OHRQoL will be re-evaluated following this treatment. A second strand aims to achieve an economic evaluation of conventional and more complex treatments. The resources needed to provide care for edentulous persons will be quantified as well as costs of treatment at an individual level. The cost effectiveness of the different treatments for the different categories of patients will be assessed on the basis of the incremental costs of achieving increments of health gain as measured by the satisfaction of patients with their treatment.

Chapter 7

Conclusions

7. Conclusions

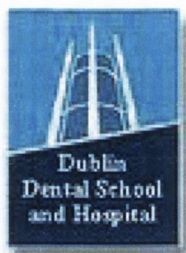
This study observed no difference in self reported status between edentulous patients who were rated less or more orally compromised, according to an objective scale of oral condition (PDI). All patient based outcomes measured in this study improved following provision of complete dentures. Both groups of patients responded similarly to the provision of complete dentures, according to the subjective assessment of their status.

Chapter 8

Appendices

8. Appendices

8.1. Participant Information Leaflet



Study Information Leaflet

To investigate whether anatomical classification of edentulism affects oral health related quality of life, nutritional status and responses to a denture satisfaction questionnaire.

What is the project about?

When people lose their teeth, changes to the gums and the mouth generally can vary from person to person. Therefore, not everybody will have the same success with wearing dentures. Some will adapt very quickly while others may find wearing dentures a big struggle. This project plans to look at the link between peoples' gum shape, their satisfaction with dentures, their nutritional status and overall quality of life. Anyone who has had all his/her own natural teeth extracted can play a role in discovering more about this important issue.

How will the study be carried out?

The study involves a once off attendance for each person to fill out three questionnaires and have an examination of their mouth by a dentist using a hand mirror. This should take no longer than half an hour. As part of the nutritional assessment, the participant's weight, standing height and their calf circumference will be measured.

No dentistry will take place. Dr. Una Lally, a dentist in full time postgraduate education at the Dublin Dental School and Hospital, will just use a small mirror to look at your gums. This examination will take place in the Dublin Dental School and Hospital.

How do I take part?

In order to participate, you must have had all your natural teeth extracted at least 3 months ago, have had a set of complete dentures made, have an x-ray of your jaws after your teeth were extracted on file at the DDSH and be at least 18 years of age.

Benefits

Taking part in the study should give you a better understanding of your clinical condition as well as assessing your nutritional status. Participants may be identified whose oral health related quality of life could be improved through treatment options other than complete dentures. These participants will be offered the opportunity to attend a further screening clinic for the restorative department waiting list at the DDSH.

Are there any risks?

No risks are associated with this study as it involves a simple examination to look at your gums using a small mirror and filling in of questionnaires.

Who cannot take part?

You cannot participate in this study if any of the following apply to you:

- You have some or all of your natural teeth
- Some or all of your natural teeth were extracted in the last three months
- You do not have a set of complete dentures
- You are under 18 years of age

- You have a learning disability
- You have communication difficulties
- You are severely ill
- You have a terminal illness
- You have a mental illness
- You are suffering with dementia

Confidentiality

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.

Compensation

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation:

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

Stopping the study:

You understand that the investigators may withdraw your participation in the study at any time without your consent.

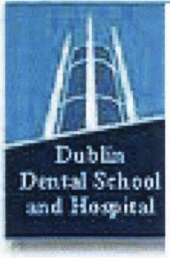
Permission:

This study has been approved by The Research Ethics Committee for Health Sciences at Trinity College Dublin.

11. Further information:

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr. Una Lally (Principal Researcher) who can be telephoned at (01) 612 7383. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

8.2. Informed Consent Form



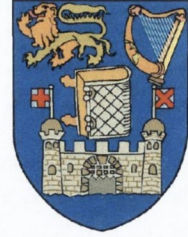
Department of Restorative Dentistry and
Periodontology,

Dublin Dental School and Hospital,

Lincoln Place,

Dublin 2.

(01)612 7324



PROJECT TITLE:

To investigate whether anatomical classification of edentulism affects oral health related quality of life, nutritional status and responses to a denture satisfaction questionnaire

PRINCIPAL INVESTIGATOR

Dr. Una Lally

BACKGROUND

When people lose their teeth, changes to the gums and the mouth generally can vary from person to person. Therefore, not everybody will have the same success with wearing dentures. Some will adapt very quickly while others may find wearing dentures a big struggle. This project plans to look at the link between peoples' gum shape, their satisfaction with dentures, their nutritional status and overall quality of life. Anyone who has had all his/her own natural teeth extracted can play a role in discovering more about this important issue.

DECLARATION:

- I agree to attend the Dublin Dental School and Hospital for a once off visit to complete three questionnaires and have a simple examination of my mouth which will take approximately half an hour.

- I agree that as part of the nutritional assessment, my weight, standing height and calf circumference will be measured.
- I have read, or had read to me, the information leaflet for this project and I understand the contents.
- I have had the opportunity to ask questions and all my questions have been answered to my satisfaction.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may withdraw or be withdrawn by the investigator from the study at any time and I have received a copy of this agreement. I understand this does not affect my access to services or legal rights.
- I agree that research data gathered for the study may be published provided that neither I nor any of my relatives can be identified as a participant.
- I agree that the data gathered may be retained after the study is completed, the material will not be used in future unrelated studies without specific permission being obtained.
- I understand that all information given by me will be treated as confidential.

PARTICIPANT'S NAME: _____

CONTACT DETAILS: _____

PARTICIPANT'S SIGNATURE: _____

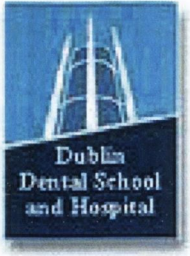
Date: _____

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE: _____

Date: _____

8.3. Letter to Prospective Participants



Department of Restorative Dentistry and Periodontology,

Dublin Dental School and Hospital,

Lincoln Place,

Dublin 2.

(01) 612 7383

Dear Sir/Madam,

I am a dentist in full time postgraduate education at the Dublin Dental School and Hospital, Trinity College Dublin. I am currently conducting a study to investigate if there is a relationship between oral health related quality of life, nutritional status, denture satisfaction and jaw classification of people with no remaining natural teeth.

This study calls on people who have had all their natural teeth extracted at least three months previously. This study involves filling in three questionnaires and one brief clinical examination as well as reviewing your existing x-rays on file at the Dublin Dental School and Hospital. As part of the nutritional assessment, the participant's weight, height and their calf circumference will be measured.

A qualified dentist (Dr. Una Lally) will perform the examination to look at your gums using a small dental mirror. This examination will take place in the Dublin Dental Hospital.

From our electronic record system in the hospital, we have identified that you wear complete dentures and because of this we invite your participation in this study.

We hope that by taking part in this study you will achieve a greater understanding of your oral condition. Participants may be identified whose oral health related quality of life could be better improved through other treatment options. These participants will be offered the opportunity to attend a further screening clinic for the restorative department's waiting list at the Dental Hospital.

You can get more information on any queries about the study, your participation in the study, and your rights from Dr. Una Lally who can be telephoned at (01) 612 7383.

Yours faithfully,

Dr. Una Lally

B.A. B. Dent. Sc. MFD RCSI

(principal researcher)

8.4. Mini Nutritional Assessment – Short Form



Mini Nutritional Assessment MNA[®]

Last name:		First name:		
Sex:	Age:	Weight, kg:	Height, cm:	Date:

Complete the screen by filling in the boxes with the appropriate numbers. Total the numbers for the final screening score.

Screening

A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?

- 0 = severe decrease in food intake
 1 = moderate decrease in food intake
 2 = no decrease in food intake

B Weight loss during the last 3 months

- 0 = weight loss greater than 3 kg (6.6 lbs)
 1 = does not know
 2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs)
 3 = no weight loss

C Mobility

- 0 = bed or chair bound
 1 = able to get out of bed / chair but does not go out
 2 = goes out

D Has suffered psychological stress or acute disease in the past 3 months?

- 0 = yes 2 = no

E Neuropsychological problems

- 0 = severe dementia or depression
 1 = mild dementia
 2 = no psychological problems

F1 Body Mass Index (BMI) (weight in kg) / (height in m²)

- 0 = BMI less than 19
 1 = BMI 19 to less than 21
 2 = BMI 21 to less than 23
 3 = BMI 23 or greater

IF BMI IS NOT AVAILABLE, REPLACE QUESTION F1 WITH QUESTION F2.
 DO NOT ANSWER QUESTION F2 IF QUESTION F1 IS ALREADY COMPLETED.

F2 Calf circumference (CC) in cm

- 0 = CC less than 31
 3 = CC 31 or greater

Screening score

(max. 14 points)

- 12-14 points:** Normal nutritional status
8-11 points: At risk of malnutrition
0-7 points: Malnourished

For a more in-depth assessment, complete the full MNA[®] which is available at www.mna-elderly.com

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