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The Predictive Value of Patient-Based Questionnaires in Treatment of Edentulism

Sittana Elfadil Hassan Ahmed

DDS (AUST), MFD RCSI

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

DECLARATION

- I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

- I acknowledge assistance from Ms. Bridget Johnston in relation to statistical analysis and the collaboration with Cork University Hospital in data collection in Cork's centre.

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SUMMARY

Statement of the problem: Edentulism is a common chronic disabling condition that impacts on an individual's health, self-perception and social interaction. Although edentulous people present with a wide range of functional and psychological needs, which may require different levels of intervention, there is no systematic approach to their diagnosis and treatment.

Aim: Identify patient groups with characteristics of edentulism that relate to choice of treatment, satisfaction and success of conventional complete dentures (CCDs) and implant overdentures (IODs).

Materials and methods: Edentulous patients attending Dublin and Cork Dental Hospitals were provided with CCDs and then offered the option of two small-diameter dental implants in the mandible. They were assessed at three time points: T1, baseline, T2, three months after the provision CCDs, and T3, three months after the provision of mandibular IODs. The interview consisted of a clinical examination (objective measures) using the Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) and a set of questionnaires (subjective measures) including Oral Health Impact Profile - Edentulous (OHIP-EDENT), Denture Satisfaction Questionnaire (DSQ), Life Orientation Test (LOT) - an optimism scale, and a Dental Treatment Uptake scale (DTUS). Patients were divided into subgroups based on T2 general satisfaction and their implant treatment preferences.

Results: 125 patients completed T1 (mean age 61 years, men 41, women 84), 102 completed T2, 21 chose to have implants, and 12 completed T3. The PDI-CE classification was

comparable for those who chose and did not choose implant treatment and also for those who were satisfied and dissatisfied after T2. The LOT scores were similar among subgroups with p-values of 0.19 for implant choice subgroups and 0.43 for T2 satisfaction groups. Those who chose implants reported significantly ($p = 0.01$) higher DTUS levels at baseline compared to those who refrained this choice (14.6 vs. 46.2). T2 satisfied patients had significantly ($p = 0.04$) higher DTUS scores at baseline than T2 dissatisfied patients (44.7 vs. 41.5). Those who chose implant treatment were significantly younger ($p < 0.05$), had newer dentures at presentation ($p < 0.05$), and reported low baseline OHIP-EDENT total scores ($p = 0.02$). The majority of participants were satisfied with CCDs (67%) compared to dissatisfied patients (22%), yet only 28% of the latter group accepted implant treatment. Fifty percent of patients reported fear of surgery as their main barrier.

Conclusions: The provision of IODs improves outcomes significantly for those who opt for this treatment. Clinical condition of the mouth and optimism are poor predictors of future denture satisfaction and patients' implant choice. The DTUS and baseline OHIP-EDENT and DSQ scores are better predictors of future satisfaction and implant choice. Fear of surgery is a major barrier to implant treatment.

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Chapter One

Literature Review

1 Introduction

To raise new questions, new possibilities, to regard old problems from a new angle, require creative imagination and marks real advance in science

- Albert Einstein

1.1 Edentulism

Edentulism is *"the state of being edentulous; without natural teeth"* (1). According to the World Health Organization (WHO) (2), it meets the International Classification of Functioning Disability and Health's definition of impairment, disability, handicap and dysfunction since an important body part which is associated with social and medical disability is lost. Total tooth loss is an incapacitating permanent condition and is described as the "ultimate marker of disease burden for oral health" (3).



Figure 1-1: Completely edentulous mouth

Edentulism can affect a person's quality of life (QoL) and daily activities in many aspects: socially, functionally, and psychologically (2, 4-7). Being edentate is a very basic indicator of oral health; hence many oral health organizations are targeted towards natural teeth preservation programs (8, 9). Edentulism continues to be a personal problem, a professional responsibility, and a continuous public health concern (9).

1.1.1 International demographics of edentulism

Edentulism is an international phenomenon. In 2010, around 158 million people globally were estimated to be edentate (2.3% of the population), and women are more commonly affected (2.7%) than men (1.9%) (10). Oral disease combined (edentulism, caries, and periodontitis) brought about 15 million "years lived with disability" (YLDs), a term used to describe life lived in less than ideal health. Those three conditions have equal shares in YLDs (10).

The prevalence of edentulism in some European countries ranges from 7% to 69% as presented in Tables 1.1 (11). The world-wide variability in prevalence can be attributed to a complex relationship between cultural, personal, socio-economic factors, access to care and intra- and inter-country variations (12, 13).

The pace of tooth loss has declined rapidly in most developed countries in the past two decades. On the other hand, given that people now live longer, the prevalence of edentulism

WHO region/Country	Percentage edentulous	Age group (years)
African		
Madagascar	25	65–74
The Americas		
Canada	58	65+
USA	26	65–69
Eastern Mediterranean		
Egypt	7	65+
Lebanon	35	65–75
Saudi Arabia	31–46	65+
European		
Albania	69	65+
Austria	15	65–74
Bosnia and Herzegovina	78	65+
Bulgaria	53	65+
Denmark	27	65–74
Finland	41	65+
Hungary	27	65–74
Iceland	72	65+
Italy	13	65–74
Lithuania	14	65–74
Poland	25	65–74
Romania	26	65–74
Slovakia	44	65–74
Slovenia	16	65+
United Kingdom	46	65+
South-East Asia		
India	19	65–74
Indonesia	24	65+
Sri Lanka	37	65–74
Thailand	16	65+
Western Pacific		
Cambodia	13	65–74
China	11	65–74
Malaysia	57	65+
Singapore	21	65+

Table 1-1: Prevalence (percentage) of edentulousness in the elderly reported for selected countries

will remain substantial (14, 15). The public's expectations are growing and a good number of edentate elderly will be very unhappy about wearing complete dentures. As this will reflect on treatment outcomes, alternatives shall be considered. Nevertheless, since the majority of complete dentures will still be for older people, this treatment modality will become more demanding, complicated and must be of a high order (16).

1.1.2 National demographics of edentulism

Edentulism in Ireland has similarities to global trends. Despite the decrease in the percentage of the edentulous population since 1979 (17), it has not and will not disappear soon (16). According to census, the population of the elderly in Ireland is rising and 11% is aged 65 or over (18).

Although considered a developed country, Ireland possesses one of the highest percentages of edentulous people (19). According to the national survey of Oral Health of Adults undertaken between October 2000 and June 2002, 40.9% of those aged 65 years or over were edentulous (17), that is; around 180,000 people (18). Among edentulous people who were 65 years or older, 6% had no dentures in 2000/02. Around 47% of edentulous adults were wearing complete dentures that are at least 10 years old. A high percentage (40.8%) of those 65 years or over was not satisfied with their dentures. Edentulism among the same age group was more prevalent in females (45.6%) than males (34.6%) and in medical card holders (45.6%) than non-holders (29.4%) - Table 1-2 (17).

	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

Table 1-2: Percentage of adults in Ireland who were edentulous by age group, gender and medical card status in 1989/'90 and in 2000/'02 (17)

Edentulism also is more evident in those with systemic diseases (classified according to the American Society of Anaesthesiologists -ASA- Classification) with percentages of 35.1%, 53.8% and 47.7% of ASA 1, ASA 2 and ASA 3 of adults respectively - Table 1-3 (17).

Age Group	ASA 1		ASA 2		ASA 3		ASA 4		Total	
	n	% Edent	n	% Edent	n	% Edent	n	% Edent	n	% Edent
16-24	1139	0.0	50	0.0	5	*	0	*	1194	0.0
35-44	914	0.8	57	2.9	5	*	0	*	976	0.9
65+	464	35.1	206	53.8	43	47.7	1	*	714	40.9

* n < 30

Table 1-3: Number of adults, and the percentage who were edentulous, by age group and general health status (ASA) (17)

1.1.3 Aetiology and risk factors for edentulism

Tooth loss is the terminal consequence of multiple etiological factors. Although total edentulism is usually acquired due to biologic processes (caries, periodontitis, pulpal disease, trauma, or cancer), it can be congenital. Caries and periodontal disease are the main two etiologic factors associated with edentulism (12). Non-biologic causes related to dental treatment include access to care, patient preference, third-party payment, and treatment options (12). Other causes include iatrogenic, traumatic and therapeutic reasons (9).

Tooth loss is strongly associated with age although it is not necessarily a consequence of ageing (13). Also, edentulousness is inversely related to income level and education. Personal and behavioural aspects such as patient neglect and poor oral hygiene are strong influencing risk factors. Other prognosticators include gender, socio-economic class, marital status, dentist/population ratio and insurance coverage (12, 13, 16).

1.1.4 Classification of edentulism

Edentate people exhibit a wide range of physical and biological differences and cannot be grouped as one diagnostic group. The American College of Prosthodontists (ACP) has established the Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) to classify complete edentulism according to the severity of diagnostic findings. This classification system can assist the dental profession to standardize the diagnostic criteria and plan suitable treatment for this group of patients. Four classes are identified, with Class I having the simplest clinical presentation and Class IV being the most compromised. The ACP has identified objective criteria to classify patients for each category (20).

PDI-CE is the first multidimensional diagnostic tool for edentulousness. The Harvard study (21) has identified its construct validity by demonstrating a high percentage of correct global diagnosis. Pan et al.(22) demonstrated good intra- and inter-examiner reliability of PDI-CE but did not find a relationship between categories of severity and patient-perceived denture satisfaction.

1.1.5 Impact of edentulism on oral and general health

Edentulism is a chronic condition that can affect basic life actions such as eating, speaking, and meeting people, which can affect negatively the social and psychological well-being of those who cannot cope (6).

Tallgren (23), in her classical longitudinal study of residual alveolar ridges reduction in complete denture wearers over 25 years, demonstrated a continual alveolar bone resorption after tooth loss which is four times greater in the mandible than the maxilla. As a result, the

height of the residual alveolar bone and the dimensions of the denture bearing area significantly diminish over time. Substantial loss can lead to soft-tissue profile changes. Furthermore, edentulous people can suffer from functional and sensory disorders of oral organs such as mucosa, muscles and salivary glands (13).

Tooth loss is a disability that impairs mastication. Bite strength and masticatory force with complete dentures falls to about one-fifth to one-fourth that of a dentate dentition (24). Denture wearers may modify their food choices and have less than an optimum diet with a lower intake of protein, fibre, calcium, iron, and vitamin C than those with a natural dentition (8).

Edentate people are in greater risks for various systemic conditions and mortality rate. Edentulism has deleterious consequences on general health as it increases the risk of cardiovascular and gastrointestinal diseases, type II diabetes mellitus, chronic renal diseases, and sleep-disordered breathing (13).

1.1.6 Treatment options for edentulism

Edentulous individuals with different clinical presentations, physical and psychological needs and co-morbidities create diagnostic and treatment planning difficulties that demand various levels of prosthetic treatment. The management of edentulism requires understanding of the chronic nature of the disorder and its association to other chronic systematic diseases (9). The prosthetic techniques to rehabilitate a toothless mouth include options that vary from a simple removable device to an implant supported fixed prosthesis. Generally speaking these comprise of three main categories: tissue-supported complete dentures, implant-retained and

tissue-supported removable overdentures, implant-supported and retained fixed complete dentures.

1.1.6.1 Conventional complete dentures

For over a century, provision of conventional complete dentures was the accepted therapy for an edentulous patient. Dentures restore appearance and function to some extent. Despite the advances in denture materials, conventional dentures, particularly the mandibular, have a reputation for discomfort as well as poor stability and retention (9, 14, 25). Over 50% of mandibular complete denture wearers suffer from compromised retention and stability, and 66% of elderly patients were not happy with their complete dentures (26, 27). Such downsides may impair a person psychosocially and physically (14). Despite all the inadequacies of complete dentures, many people are satisfied, adapt well to their disability and manage to eat, talk and function with these prostheses (6, 28-30). For those who struggle to adapt, alternatives must be considered (31).

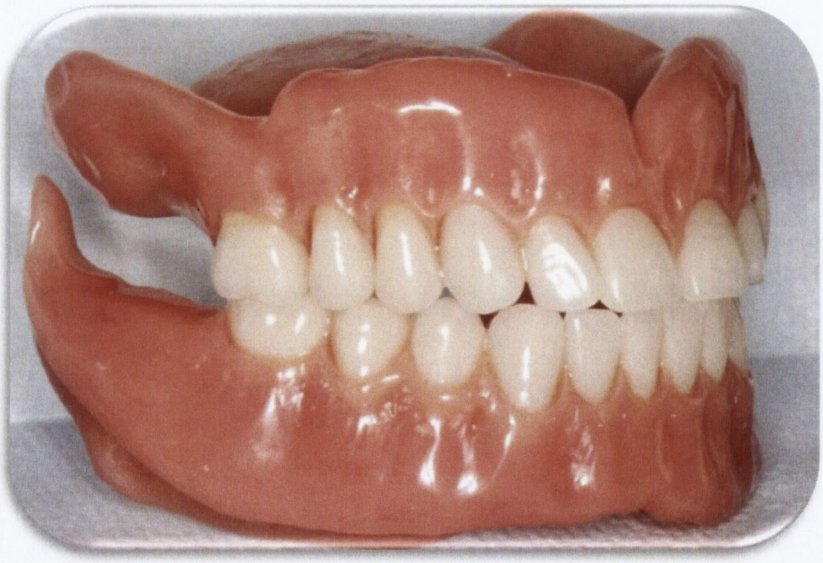


Figure 1-2: Conventional complete dentures

Denture wearing compared to natural teeth may be associated with less self-confidence, premature ageing, distorted self-image, and changes in social activities and interrelationships (5). Compared to no teeth dentures improve appearance and socializing, which may improve self-image and psychological well-being (13). For certain people where age, oral and general health and socio-economic status conditions allow, complete dentures can be a safe, predictable, and economic treatment option (29).

The construction technique and denture quality do not relate directly to denture success unless there is an obvious technical fault (denture base extension, jaw relation) that may identify the reason for dissatisfaction (25). On the other hand, the literature strongly points towards patient-related factors as key factors to success (6, 9).

1.1.6.2 Implant-retained and tissue-supported prostheses

The introduction of dental implants, and consequently implant overdentures, overcame many drawbacks of conventional denture treatment. By improving stability and retention, implants addressed several functionality problems so that an implant-retained overdentures was considered by the McGill (14) and York [4] consensuses as the "minimum offered first-choice standard of care for the edentulous mandibular arch". Despite these consensuses and the widely available high-level supporting evidence, the provision of implant overdentures is not a routine treatment (14). Cost and provider expertise are the probable barriers against this conceptual shift in therapeutic philosophy.

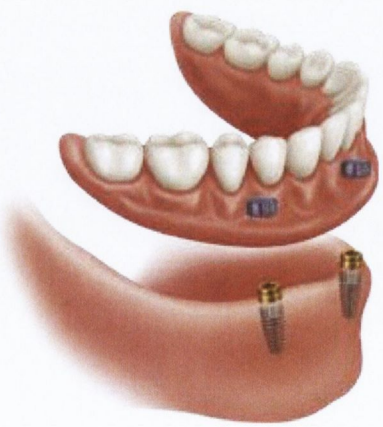


Figure 1-3: Implant overdenture

Burns concluded in his review (26) that the following general consensus about mandibular dentures is substantiated in the literature:

- Compromised retention and stability negatively impact the treatment outcomes of conventional dentures
- Implants demonstrate remarkable success rates in the anterior mandibular region and they also slow the bone resorption rate
- Implant mandibular overdentures have many benefits over conventional dentures rendering the former a superior treatment choice from a patient satisfaction point of view
- Peri-implant tissue and bone react favourably in overdenture treatment
- There is a potential for complications that necessitates a structured maintenance scheme with implant overdenture treatment

Implant overdentures offer many advantages over implant-supported fixed prosthesis: they are less expensive and provide better accessibility for oral hygiene and less food impaction, with no significant difference regarding function and patient satisfaction (9, 32, 33). Some long-term denture wearers have expressed a preference for overdentures over fixed-implant prostheses (32).

1.2 Implants for overdentures

An implant overdenture is a relatively simple, minimally invasive and affordable treatment modality. Dental implants, specifically in the anterior mandible, have a remarkable long-term survival rate of about 95% with few serious complications (26). In addition, implants decrease the alveolar bone resorption rate (34). A great bulk of literature, of which many are

randomised controlled trials and systematic reviews, supports the superiority of mandibular implant-overdentures over their conventional counterpart from a general satisfaction and oral-health quality of life viewpoint, regardless of the implant anchor system (14, 15, 35). This is probably due to an improvement in denture stability, retention, comfort, chewing ability and nutrition (15, 36). A systematic review (37) validated that the masticatory ability of mandibular implant overdentures is significantly improved over conventional dentures, but only where ridges are severely resorbed and/or mal-adaptation to conventional treatment is evident.

1.2.1 Number of implants for overdenture treatment

Various numbers of implants ranging from one to four have been advocated for mandibular implant overdentures. McGill (15) and York (14) consensus statements recommended two implants. Four versus two implants have been shown not to be significantly different regarding implant survival, complications and patient satisfaction. Hence, a two-implant overdenture is advantageous given its cost-effectiveness, prosthetic simplicity and surgically minimal invasive nature (33, 38). Reducing the number further to one implant has also been advocated (39). Although promising, single implant overdentures may pose complications related to anatomical factors and residual ridge resorption. Further evidence is still required (38).

1.2.2 Attachment system for implant overdentures

Common anchorage systems for implant overdentures can be classified as: (1) resilient stud attachments on un-splinted implants (for example locator and ball attachments), (2) resilient

clip attachments on rigid bar joining implants, and (3) magnet attachments. It is concluded that overdentures may maintain health and excellent prognosis irrespective of retention systems used over ten years of service (40). One review (41) has stated that there is no significant difference in stress distribution between free-standing and splinted attachments provided that the overdenture is well-designed and treatment conditions are controlled. A high level of evidence cannot suggest significant superiority of one attachment system over the other but there is reasonable evidence to suggest inferior satisfaction with magnets (42). Bar and clip attachments tend to show a need for less aftercare (43). It is uncertain which attachment is best biomechanically. Mericske-Stern (44) advocates selection based on a particular clinical scenario and specific patient's needs.

Although un-splinted two implant-overdentures provide lower retention values than splinted implants, this difference is not reflected in patients' satisfaction ratings. Furthermore, two-implant retained overdentures exhibited no difference regarding implant failure, marginal bone levels, probing attachments whether the implants were splinted or not (45). Therefore, the simplest treatment form (single stud attachments) is sufficient (46).

1.2.3 Size of implants for overdentures

1.2.3.1 Small-diameter implants for overdentures

The use of osseointegrated dental implants has demonstrated long term success in the rehabilitation of edentulous patients. The diameter of standard-sized implants (> 3 mm) has constrained their use where bone volume is limited. The introduction of reduced-diameter 'mini' implants (< 3 mm) was proposed to increase the number of sites where implants could be used and reduce the need for bone augmentation (47). Additional proposed benefits

include potential cost reduction with mini-implants, minimization of discomfort and surgical trauma and the possibility of immediate loading in patients who could not have been treated with implants otherwise (48, 49).

Slightly more bone loss was observed by Jofre et al. (50) around two small-diameter implants in comparison to standard-diameter implants. This was attributed to increased moment loads due to higher the flexural modulus in small-diameter implants and subsequently increased peri-implant bone resorption. On the other hand in a review by Renouard (51), bone loss around reduced-diameter implants was found to be comparable to that around standard-diameter implants. Treatment with mini-implants may be less predictable in the maxilla and with short implants(52).



Figure 1-4: Small- and regular- diameter implants

Though the cost of implant treatment can be an issue for edentulous patients, another obstacle is anxiety about surgery (53). Interestingly, in one study even when implants were offered for free, 36% of edentulous patients refused treatment mainly due to apprehension about surgical risks (54). Small-diameter implants may offer a more appealing treatment option with similar success, especially if a flapless protocol is used (53). Certainly, the possibility of immediate restoration of mastication and aesthetics for patients during the healing period is an advantage of small-diameter implants (55, 56).

Implant overdentures retained by small-diameter implants can be a successful treatment modality for mandibular edentulism since it has shown improved QoL, satisfaction and chewing ability in short term research (57, 58). Nonetheless, there is less clinical data to support the use of small diameter implants compared with standard implants placed and

restored with conventional protocols. The long term success of mini-implants placed with a flapless protocol, unsplinted and immediately loaded, remains to be demonstrated.

1.2.4 Success of implant overdentures

It has been reported that dentures retained by narrow-diameter implants provide good patient satisfaction; and clinical success and survival rates for these implants are acceptable (55, 59, 60). A recent literature review (53) has examined the survival of 10,093 small-diameter implants in 22 studies with follow up duration ranging from 5 months to over 9 years. Survival rates were comparable to those of standard width implants which ranged from 95% to 99.9% (53).

1.3 Treatment outcomes

Decision making in dentistry involves an appreciation of the outcome of treatment measures that compare the benefits of one treatment option over another. Guckes et al. (61) have identified four categories of treatment outcomes for implant treatment:

- Survival/longevity (implant and prosthesis survival, mortality and morbidity)
- Physiological/Physical (masticatory efficiency, bite force, bone level, nutrition impact)
- Behavioural/psychological (appearance, body image, quality of life, treatment satisfaction, self-esteem)
- Economic impacts (direct and indirect costs of treatment and maintenance)

The literature describes many outcome measures designed to evaluate chewing, denture satisfaction, personality, self-confidence, body image and psycho-social well-being. Those scales are either standardized; of known validity and reliability, or ad hoc; developed by investigators for the purpose of the research (62). The choice of which clinical outcome is used depends on the question asked and who is asking. Each researcher has a different hypothesis to test and each party in the treatment process (patient, clinician, treatment payer) has different concerns. Thus, no one universal outcome scale exists to measure treatment outcomes in prosthodontics (63).

Increasingly, researchers measuring health outcomes have shifted from clinical and technical scales (objective) towards incorporating patients' perceptions of health and well-being (subjective) (64). Patient-based responses are critical since patients' perceptions can be weakly related to professional ratings of the same variable. Subjects showed that they are better off expressing their opinions based on their own values and experiences. Utilizing strictly and solely objective clinical measures is criticized since it overlooks the psychosocial side and the patients' perceptions of health condition, function, and individual needs (13, 63, 65). Medical research has realized the value of subjective measures and used them extensively especially in cancer treatment research (66) and chronic illnesses research such as diabetes mellitus (67). Similarly, various dental specialities used study designs with subjective patient-based outcomes. For example, in orthodontics de Paula et al.(68) investigated the self-perceived dental aesthetics in malocclusion and found it to be influenced by the oral health-related quality of life and body satisfaction. In prosthodontics, edentulism was studied extensively using combinations of subjective measures. All four recent systematic reviews (29, 35, 42, 69) comparing and investigating effects of conventional and

implant prostheses have highlighted that denture satisfaction and oral-health quality of life are the most important patient-centred outcome measures in the management of edentulism.

1.3.1 Quality of Life

Quality of Life (QoL) is a term that was initially identified in 1920 but not used extensively and in its today's context until 1960s (70). Since then, many definitions have evolved. QoL is a phrase used to embrace several notions including health status, function, and life circumstances (13). QoL is defined by the WHO as *"an individual's perception of his or her position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment"* (71). It is important to find out how satisfied or not a person is about a particular aspect of his/her life, keeping in mind that this can be highly individual (64). QoL differs between and within people. It changes over time for the same individual due to variation in experiences or any of its constituting elements (13, 72). For example, changes in psychological patterns such as adaptation, self-control, and expectancy can modify and change attitude towards the same event over time (72). QoL is a multidimensional term that considers variable aspects of life (73) and relates to how personal hopes may match with an individual's experience (74).

Broadly speaking, QoL has subjective (sense of well-being) and objective (functional status and pursuit of interests) perspectives (73). Markers of health status and quality of life are considered "patient-based" measures as they reflect the patients' perception of and psychological reaction to the therapy. Since patients' motivation in seeking denture treatment

is derived from issues of psychosocial well-being, comfort, function, confidence, aesthetics, and patients' perception on treatment, quality of life is a fundamental asset in planning treatment (62).

WHO have defined health as *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"* (75). Health-related quality of life (HRQoL) has emerged from understanding this multi-dimensional definition which incorporates the physical and psycho-social elements of well-being. HRQoL is defined as the *"optimum levels of mental, physical, role (e.g. work, parent, carer, etc.) and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being"* (73). The relationship between edentulism and general health seems to be multidimensional and multidirectional. A conceptual model was created by Emami (76) to demonstrate those pathways (Figure 1-5).

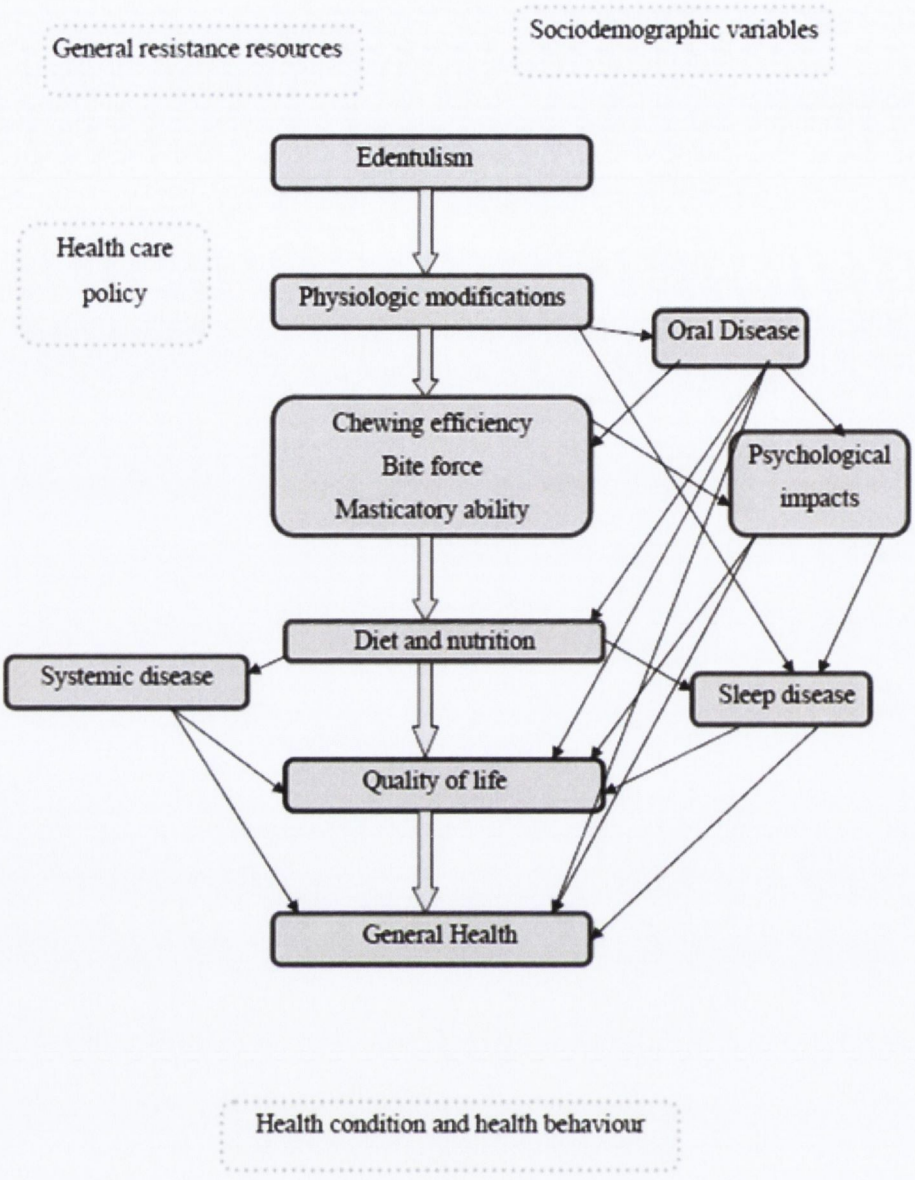


Figure 1-5: **Conceptual model showing pathways for the edentulism-general health relationship (76)**

1.3.1.1 Quality of Life in oral health

In line with the medical field, conceptual thinking in oral health is changing with the emergence of theoretical models that link body and mind factors and the development of measures that test these models (77).

Oral health-related quality of life (OHRQoL) was first described by Gift et al. in 1992 (78) as *"the self-perceived information particularly related to oral health. This include the functional (e.g. eating, speaking), social (e.g. meeting other people), and psychological (e.g. self-image, self-esteem) impacts of oral disease to general well-being"*. Since the recognition of OHRQoL as a valid factor in patient evaluation in almost every aspect of physical and psychosocial oral healthcare, many instruments have been developed (79). OHRQoL can be used to assess both negative and positive perceived oral health outcomes (79).

OHRQoL is important since: (1) oral health can affect general health; (2) patient-centred information is becoming more evolved in the decision-making practice, (3) the necessity for evidence-based practice is widely known, (4) traditional scales failed in management of many conditions (80). More and more, appreciation of the importance of patients' perceptions of oral health is expanding in the estimation of general well-being and healthcare outcomes (13).

1.3.1.2 Measuring Oral-Health Related Quality of Life

OHRQoL is usually measured using a questionnaire whose results act as an outcome that can indicate at a given time how the oral condition is affecting the person's quality of life and well-being (81). QoL instruments can be disease-specific or generic. The former are used to examine the influence of a particular condition on body parts and function that are relevant to the disease, while the latter reveal the influence of a condition, or many conditions, on general health status, well-being and quality of life (76, 82). Usually they are used separately, but generic and disease specific instruments can be used together to assess QoL in edentulism (82). One limitation of the general QoL measures is that can be less sensitive and/or responsive in comparison to site-specific measures in detecting changes in outcome from a

specific treatment in the oral cavity or to an oral clinical condition (76). This is because generic measures may be affected by relevant external conditions if used in specific cases and consequently may miss responsiveness. Rather, a specialized measure can be developed to be more appropriate, provided it suits the population, shows adequate responsiveness to changes resulting from treatment, demonstrate evidence of reliability (gives same result if re-tested in the same sample), content validity (covers all relevant aspects of the outcomes of interest), and construct validity (related to other scales in the expected way) (63).

Since 1997, many OHRQoL instruments have been published, examples are shown in Table 1-4 (83).

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

Table 1-4: Oral health outcome measures - Adapted from Locker D and Allen F, 2007 (83)
(Marked with* are the most commonly used)

Some of these scales are ambiguous regarding their construct validity (what actually these tools are supposed to measure) as well as their importance in the target-population. Furthermore, some scales are claimed to be patient-centred while they are in fact expert-centred (83). Locker and Allen (83) have proposed guidelines to assess outcome measures of OHRQoL - Figure 1-6:

Did the investigators conceptually identify what they meant by quality of life?
Did they state the domains they wanted to measure as components of quality of life?
Did the investigators give reasons for choosing the instruments they used?
Did the investigators aggregate the results from multiple items, domains or instruments into a single composite score?
Were patients asked to give their own global rating for quality of life?
Was overall quality of life distinguished from health-related quality of life?
Were patients invited to supplement the items listed in the instruments offered by the investigators?
If so, were these supplemental items incorporated into the final rating?
Were patients asked to indicate which items were personally important to them?
If so, were these importance ratings incorporated into the final rating?
Do the authors show that aspects of patients' lives they have measured are important to the patients?
If not, have previous studies demonstrated their importance?
Do the investigators examine aspects of patients' lives that clinical experience indicates patients value?
Are there aspects of HRQL that are important to patients that have been omitted?
Were individual patients asked to directly place a value on their lives?

Figure 1-6: Criteria for evaluating health-related quality of life measures

In a research context, OHRQoL measures can be used as a survey tool to look at trends in oral health and population-based needs. Oral healthcare planners can gain much from indentifying individual characteristics and needs when planning for population-based policy models. In clinical studies, OHRQoL can be used as an evaluative outcome measure. For example, in longitudinal trials; pre- and post- intervention assessment can indicate service users' perceptions of treatment effectiveness and efficiency, and can be used to evaluate quality and improved care (79).

1.3.1.3 Oral Health Impact Profile questionnaire

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"* (84). OHIP is a

widely used questionnaire and considered the most comprehensive and sophisticated outcome scale of OHRQoL (85). OHIP was developed by Slade and Spencer in 1994 (84) to measure the impact of oral health on the quality of life. It evaluates the self-perception of the "social impact" of oral conditions on someone's life and well-being, taking into account the dysfunction, discomfort and disability caused by the oral disorder (84).

OHIP has seven dimensions, namely: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap (84). These domains have emerged from the theoretical conceptual framework model of oral health by Locker (86) (Figure 1-7) which in turn is based on the WHO classification of impairment, disability and handicap (2). This model represents a major shift in the dental care towards patient-oriented care (87). Complete edentulism fits Locker's model and WHO's classification since it is considered an impairment (a part of the body is lost), disability (impedes on ability to carry daily functions including chewing and speaking), and handicap (embarrassment of meeting people due to dentures) (88).

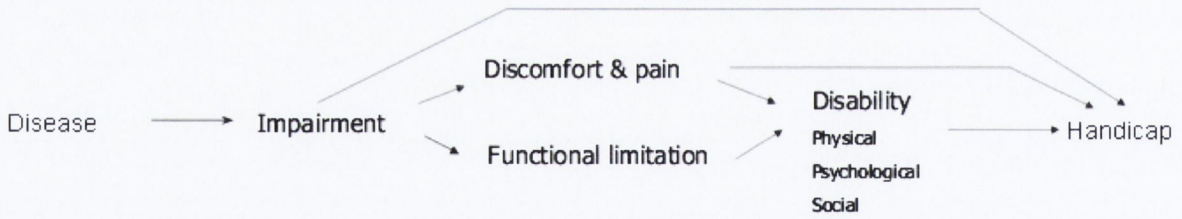


Figure 1-7: Conceptual model for measuring oral health - Locker, 1988

As opposed to generic tools, OHIP is used when greater sensitivity to the oral health condition is needed since it can reveal changes in variables or results of interventions related particularly to the condition in question (76). All the main features of instrument assessment (reliability, validity, interpretability, responsiveness, conceptual and measureable model,

respondent and administrative burden, alternative forms, cultural and language adaptation) have been met by the OHIP which make it a good fit to its original model (84, 85, 89).

OHIP is available in either in full or short format. The original full OHIP version developed by Slade (84) consisted of 49 items distributed among the seven domains mentioned earlier. Responses are in Likert response format, that is; 1 = never, 2 = hardly ever, 3 = occasionally, 4 = fairly often, 5 = very often. Calculation can be done for each domain as a subscale or all items for the total impact level. OHIP-49 was found to be lengthy and time consuming (it takes around 20 minutes to complete), a limitation for use in clinical research, especially with old participants (85). Furthermore, it might not be sufficiently specific regarding some research questions, especially for an edentulous population where it contains irrelevant items such as toothache and tooth sensitivity. This may compromise the power of the questionnaire to detect impact on OHRQoL (76). Although Slade evaluated and provided construct validity to OHIP-49 (84), Baker el al. (87) questioned its construct validity after structure equation modelling analysis. However, he concluded that his tested sample size was inadequate to draw final conclusions.

To overcome the above limitations, efforts were made to shorten OHIP-49 without adversely affecting the instrument's outcome characteristics. In 1997, Slade shortened the OHIP full format into a 14-item scale using a statistical regression procedure (90). Although simplicity, validity, reliability, precision and ability to discriminate between groups were met for OHIP-14 (85, 90), Allen and Locker (91) debated its validity and appropriateness when the target population are edentulous, since many questions relevant to denture wearing and chewing were removed. Hence, "floor effect" (not being able to perceive improvement after treatment) can occur.

1.3.1.4 A modified short version of OHIP for edentulous adults

Using item impact reduction method, Allen and Locker in 2002 developed and validated another shortened version of OHIP, the "OHIP-EDENT" outcome measure targeting OHRQoL in an edentulous population (91). In this instrument, the full OHIP-49 was reduced to 19 questions but still covered the original seven domains. OHIP-EDENT was derived from British and Canadian data. The measurement properties of OHIP-EDENT are comparable to the original OHIP-49 and demonstrate good discriminate validity, responsiveness, and sensitivity to change. It addressed shortcomings of OHIP-14 as being less vulnerable to floor effects, and more appropriate for edentate people (91). OHIP questionnaires have been used in an Irish edentate population (7, 92) including the OHIP-EDENT questionnaire (93, 94).

1.3.2 Patient satisfaction

Patient satisfaction is an emerging discipline of research that possesses enormous potential in outcome measures for clinical trials and research. It has been suggested that patients' satisfaction is more sensitive to changes after intervention than QoL, particularly for chronic conditions such as edentulism. Furthermore, it is a sensitive outcome measure for many treatment interventions (95). It is a very important patient-mediated outcome measure as it allows the direct quantification of patients' judgments on various features of a given treatment (96). Thomason et al. (42) indicated that denture satisfaction is a suitable outcome measure when the answer to "how patients perceive the benefits of their treatment?" needs to be established.

In prosthodontics, general satisfaction is justified as a primary outcome measure since it is sensitive in differentiating and detecting clinical changes in patients' rating among different prosthetic designs (97, 98). In complete edentulism, patient satisfaction with mandibular conventional dentures is multi-factorial with self-reported instability and pain being the main resources of dissatisfaction (9). Moreover, 89% of the variation in the scores of patient satisfaction was comprised of ratings of combined features of complete dentures (level of comfort, stability, ease of chewing, ability to speak and aesthetics) which were recognized as vital aspects by both dentists and patients (98). Patients' satisfaction has been linked to many factors, such as patients' expectations, choice of food, denture security, and retention (93, 99, 100). Although age has not been a consistent predictor for patient satisfaction, Awad and Feine (98) have found that gender is a highly significant factor where females were more satisfied than men with complete dentures. Vernoon et al. (99) found no association between denture satisfaction and years of denture wear or number of previous dentures. It was also concluded that clinical examination is not a suitable predictor of prosthesis satisfaction and when patients were requested to reveal their views of their dentures, their evaluation was dissimilar from that of the clinicians (98).

1.3.2.1 Measuring satisfaction with dentures

Most of the denture satisfaction questionnaires are ad hoc scales tailored to answer specific questions. They are classified into categorical scales (CAT) or visual analogue scales (VAS) usually using a 100 mm VAS.

Simplicity and comprehensibility in clinical research are some of the characteristics of denture satisfaction tools. Disadvantages include the overestimation of satisfaction rating,

especially with implant treatment, causing a "ceiling effect" (Scores that are concentrated at the top of the scale). This effect is more evident in categorical scales and may compromise the sensitivity and power of an instrument (101).

1.3.2.2 Denture satisfaction questionnaire

A denture satisfaction questionnaire (DSQ) was adapted from Tang et al. (102) and validated by de Grandmont et al. (103). The DSQ has eleven items. Four variables (comfort, stability, ability to speak and ability to chew) were derived from patient-mediated qualitative research to identify the most important denture features. They were tested and found to be contributory to satisfaction (98). The remaining seven factors are: patients' general satisfaction, quality of meals, choice of food, socialization with dentures, denture being a foreign body, self-confidence and general change in life caused by a denture. These factors were also found to be associated with satisfaction in other studies (93, 99).

In the DSQ, patients rate their existing denture on a Likert scale of six points, ranging from "6=All of the time" to "1=None of the time". General satisfaction with the mandibular denture is rated on a four point scale "1=Not satisfied", "2=Neither satisfied nor dissatisfied", "3=Fairly satisfied" and "4=Very satisfied". Participants were asked to choose the phrase that best described their perception. This scale was previously validated (103) and used reliably in an Irish edentulous population (93, 94).

1.3.3 OHRQoL and Denture satisfaction outcomes in edentulism and its treatment

Evidence strongly indicates that tooth loss may cause a negative impact on oral health-related quality of life, indicating inferior QoL (104). This can be caused by restriction in mastication and speech, biological trauma, aesthetic worries, or undesirable self-perception, since teeth play a vital role in appearance and daily essential tasks (13). Although edentulism is known to adversely affect oral function, it also negatively impacts on social life (105) and intimate relationships (36). Edentulism is significantly associated with less social participation in daily activities due to embarrassment in speaking, chewing, smiling and interrelating with others. This may undermine the feeling of self-worth, leading to isolation and sadness (106).

Social indicators through subjective assessment have been used to complement traditional clinical measurements in edentulism (59, 85, 107). Psycho-social outcome measurements widely used for total edentulism are OHRQoL assessments together with treatment satisfaction scales (92, 93, 97, 108-110). There is a high positive correlation between these two outcomes (96). It should be clear that, although complementary, OHRQoL and patient satisfaction are distinct measurements in nature (101). The former is directly related to the influence of a treatment modality on a patient's health condition and well-being, while the latter is directly related to the treatment itself. The features that affect those measures may be dissimilar. For instance, satisfaction with treatment may vary with treatment preference and expectation, which in turn may have little or no effect on OHRQoL since it is not related to the treatment's nature (96). Additionally, Michaud et al. (96) has studied the degree of association between OHRQoL and satisfaction in an edentate population and found that they were associated only through two variables: chewing ability and oral condition.

A good number of high-level evidence studies -level I & II- (42, 92, 93, 97, 108-110) have compared the OHRQoL and denture satisfaction outcome measures in conventional complete denture treatment versus mandibular implant overdentures. Although many patients adapt to conventional dentures, patient satisfaction and OHRQoL can be improved significantly if support was gained from as few as two implants (100, 108, 111). Based on patient-centred outcomes, the European workshop on Evidence-Based Reconstructive Dentistry concluded in its systematic review that mandibular implant overdentures have a greater treatment effect than conventional dentures (42), although the magnitude of this impact is unknown (35). A meta-analysis of seven randomized control trials (35) concluded that patients are more satisfied and had better patient-subjective ratings when treated with implant overdentures then conventional dentures. Patient satisfaction reached both clinical and statistical significance with pooled ES 0.80, z = 3.56, 95% confidence interval (CI) 0.36 to 1.24 P = 0.0004, while the pooled ES for OHRQoL was -0.41, z = 1.31, 95% CI -1.02 to 0.20, P = 0.19. Therefore, implant overdentures may be most suitable for those with advance residual alveolar ridge resorption or denture mal-adaptation issues. Nevertheless, complete dentures can be a satisfactory treatment for those who manage to adapt to them (29, 69).

The OHIP is significantly reduced by the provision of a two-implant overdenture, indicating a clinical improvement (69). This was demonstrated by the Montreal group (108) in a randomized control study with significant reduction in all seven dimensions of OHIP. In the same vein, a significant reduction in OHIP scores was found by Allen et al. (100) in complete denture wearers who requested and received conventional dentures and complete denture groups who requested and received implant overdentures, but not in the complete denture group who requested implant overdentures and received conventional dentures. A significant improvement in the OHIP score with conventional dentures has been established when

patients can adapt well to them (100). Pre-treatment rating of OHIP, treatment allocation, age, gender and marital status are variables that can explain changes in OHRQoL scores (108).

Compelling high-level evidence (42) suggests that patient satisfaction with implant overdentures is significantly greater than with conventional dentures, although there is an improvement in satisfaction with both treatment modalities. In a randomized control study, Harris et al. (93) has shown that new complete dentures produce a significant improvement in satisfaction and a subsequent improvement is produced with conversion of the new dentures to implant overdentures. Patients were approximately 36% more satisfied with implant overdentures (101). Implant overdenture patients rated comfort, stability, and ability to chew to be significantly higher than the conventional denture group. Thomason et al. (101) explains that this satisfaction tends to stabilize over time with conventional dentures, while it shows a continued pattern of improvement with implant overdentures. Reported satisfaction with conventional dentures ranged from 65% to 90% (112).

1.3.4 Dental treatment uptake by edentulous patients

In 2013, Meaney et al. (113) undertook qualitative research among a sample of the Irish population investigating perspectives on edentulousness. Sixteen edentulous patients, aged 59 to 83 years, of whom 12 were women and 4 were men, participated in semi-structured interviews. The aim of this work was to explore experiences of edentulousness and attitudes towards dental treatment options. The qualitative analysis indicated that participants experience deep dissatisfaction with the functionality of their dentures both in terms of mechanics and aesthetics. However despite the evidence of such deep dissatisfaction with

current dentures there was an obvious reluctance from participants to pursue dental treatment (new dentures or implant treatment). These findings were the basis for the same authors to develop an original specific scale that aims to explore in depth dental treatment uptake by edentulous patients. Such a tool is beneficial in discovering edentulous patients' rationale in accepting one treatment over another. Van Waas (107) has found that examining patient's attitude towards dentures before treatment is a prospective tool for denture satisfaction. Those with positive opinions and realistic expectations were more satisfied with their dentures.

1.3.4.1 Dental Treatment Uptake Scale

The findings from the qualitative study by Meaney et al. (113) indicated that there were a number of intrapersonal and social reasons why an individual may consider undertaking treatment. Therefore, the authors aimed to develop and design a scale which would assess the likelihood that individuals would undertake dental treatment. The Dental Treatment Uptake Scale (DTUS) was developed to capture how specific treatment satisfaction, perceived benefits and social factors might motivate participants (113). The DTUS is a categorical scale constituting of 11 statements. Responses reflect the degree of participants' agreement or disagreement on a Likert scale of five possible answers ranging from "1=strongly disagree" to "5=strongly agree". This scale surveys edentulous patients' attitudes towards: trial of new treatment, consideration of implants if provided for free, replacement of dentures, painful dental treatment, dentist recommendations for treatment, and improving lower denture fit.

1.3.5 Psychological parameters

Although psyche was considered a significant key in determining edentulous patients' ability to cope with dentures (114), research on the psychological influences is still limited. Locker (62) was unsure about measuring personality as an outcome measure since it is a stable quality of a person that is unlikely to alter by edentulism nor therapeutic intervention. On the other hand it is a strong quality that can alter an individual's prospects and attitude towards certain treatments. Personality traits are suggested to be useful predictors in patient behaviour and treatment selection, prompting dental literature to examine psychological effects on satisfaction and treatment acceptance (115)

Many investigators have used different instruments in dentistry to measure various aspects of personality. Although validated, they are quite long questionnaires. Examples include (107, 116):

- Neuroticism Extraversion Openness Five-Factor Inventory (NEO-FFI) scale. This questionnaire consisted of 60 items.
- Eysenk Personality Inventory (EPI) test
- Tennesse Self-Concept scale
- Wilde Neurotic Lability scale
- Health locus of control scale

A negative relationship was found by some researchers (114, 116) between neuroticism and satisfaction with dental treatment in patient receiving dental implants and complete dentures. On the other hand, others failed to demonstrate such a relationship with personality patterns (107).

Optimism is a personality characteristic that can be defines as *"A mood or attitude associated with an expectation about the social or material future, one which the evaluator regards as socially desirable, to his or her advantage, or for his or her pleasure"* (117). Optimism is a psychological concept that is closely related to many aspects of health and well-being since *"optimists emerge from difficult circumstances with less distress than do pessimists"*. It is also related to coping attitudes since *"optimists seem intent on facing problems head-on, taking active and constructive steps to solve their problems; pessimists are more likely to abandon their effort to attain their goals"* (118). In 2013 a meta-analysis of optimism found that it is positively correlated with life satisfaction (119). This may indicate that those who are more optimistic may perform better under treatment and have better satisfaction outcomes than pessimistic individuals. Optimism is a psychological asset that is found to show a relationship with the person's QoL, especially the way an individual copes with disease and poor health (79).

1.3.5.1 Life Orientation Test

There are many ways to measure optimism including the Life Orientation Test (LOT). The LOT was originally developed by Scheier and Carver in 1985 (120) and became one of the most popular optimism tests. There are eight main statements (plus four additional filler statements) divided between four positively and four negatively worded items such as " I'm always optimistic about my future" and "I rarely count on good things happening to me" respectively. LOT has been revised and two other versions are available: LOT-Revised and Extended LOT. The three formats are commonly used since they all measure dispositional optimism; that is expecting positive outcomes (121). LOT was chosen for this study because

of its simplicity, ease of use by both investigator and research participants, and because it is short. It does not add significantly to the participant interview time. Predictive and discriminate validity and reliability for LOT has been previously established (120, 122).

2 Aims and objectives

2.1 Rational for current study

Edentulous individuals with different presentations and psychological needs demand diverse levels of prosthetic treatment. Evidence suggests that complex interventions have proven to be advantageous to many patients, especially those with advanced alveolar bone resorption (111). Nevertheless, some patients refuse implants, (110) while others do not seem to show the expected significant improvement after implant treatment in comparison to conventional care. The fact that a prosthesis of reduced quality may be well tolerated in one individual, while a well-fabricated denture may be a disappointment in another has been a repeated source of uncertainty and annoyance for the dental profession and the patient (25). Although implant technology has added greatly to the care of edentulous people, it is found that many denture wearers neither want nor need this type of intervention (59, 123). Then again, health care providers have been slow to provide implant treatment (59). The provision of, and access to care for edentulous patients is random, disorganized and unequal so that the need for policy and practice changes is quite compelling. Especially now, people with financial constraints, third-party payers, and governments must develop priorities to make the best use of scarce health care budgets. The funding of the Health Research Board (124) for this project originates from its understanding this "research to practice gap" in Ireland (125).

Thomason (31) suggests that heterogeneity in edentate patient-centred outcomes indicates presence of sub-groups. To date, there is no methodical diagnostic instrument to point out the level of patient need and properly match the sub-group with the most likely successful intervention. The available management approaches focus mainly on objective (anatomic/functional) measures and ignore the other side of the coin; namely patients' concerns, although the latter is now known to be equally —if not more— insightful clinical information (69, 126). Literature confirms that the satisfaction of complete denture wearers is not directly associated with the physical condition of the mouth or denture quality (59). It is believed that both subjective and objective assessments are necessary in understanding the dental needs, evaluating success and failure, and predicting treatment outcomes for edentulism (59, 126).

There is little in the literature about prognostic factors that may influence the successful restoration of an edentulous patient. Since denture treatment may impact on patients' quality of life and a conventional denture or implant-retained denture has resource implications on the patient and health authorities, it is necessary to pinpoint those factors associated with success (127). The use of patient-perceived measures such as OHRQoL and denture satisfaction can help to direct resources towards the most needy. Anderson (63) proposed that there are no outcome scales yet that indicate which individuals benefit most from implant-level prosthesis. At the present time, research has failed to furnish the clinician with a practical method whereby patients who are unlikely to accept full dentures can be identified with any degree of certainty.

In order to properly identify the predictive value of patients' data that would indicate the most appropriate treatment for an edentulous person, both objective and subjective criteria should

be considered. While the value of patient-reported measures has been mentioned, it has not been proven that these alone can be used to construct an index of treatment need, or probable success. There is little understanding of how an individual arrives at a self-assessment of their oral status and treatment preference. To date, there has been no systematic attempt to combine the objective anatomic/physiologic deficit of patients with their subjective assessment, to reach a full understanding of their status and treatment needs. Our central reasoning is that both subjective and objective assessments of an edentulous patient are required to predict treatment need, and particularly, for the identification of sub-groups. For example, it may be that of the patients who perceive their oral status to be poor are only those with severe alveolar bone resorption who would benefit from implant treatment. Conversely, it may be that maladaptive patients would be likely to fail with conventional denture treatment, regardless of their anatomic deficit. So, while patient treatment preference is known to be a predictor of success, it may be that objective criteria are needed to establish a priority for treatment need. At the very least, a clear and consistent set of diagnostic parameters will be useful in the characterisation of patient groups and for treatment provision.

This is a conceptual study undertaken to investigate on the theoretical and hidden links between edentate patients' characteristics and treatment outcomes.

2.2 Hypothesis

That a combined set of clinical and patient-centred baseline data can be used to suggest the most appropriate treatment option for edentulous patients.

2.3 Aim

Identify target groups with characteristics of edentulousness that relate to satisfaction and success of conventional complete dentures and two-implant overdentures.

2.4 Objectives

The objectives of this study are to:

1. Investigate edentulous patients' degree of satisfaction at either baseline (T1), or after conventional denture treatment (T2), then to re-assess following implant-based treatment (T3).
2. Evaluate the Oral Health Impact Profile for Edentulous adults after new complete denture and implant overdenture treatment
3. Classify PDI-CE diagnostic complexity of patients
4. Examine the psychological trait of optimism of the participants using Life Orientation Test
5. Investigation of the scores of "Dental Treatment Uptake Scale " in the edentulous sample
6. Compare those who did choose implant treatment against those who did not and examine characterisation of sub-groups that may indicate treatment choice.
7. Investigation of groups based on satisfaction and examination of baseline key elements of edentulous patients that can indicate satisfaction and success for treatment of edentulism.

This research is part of a project that was started previously by Dr Una Lally in DDUH to investigate the nutritional aspect of conventional dentures (94). It has another economic dimension which is under current investigation by Dr Eamonn McGlynn.

2.5 How will this research contribute to the field?

A considerable portion of Irish edentulous people (47%) are medical cards owners; hence their denture treatment is covered by HSE. Of adults aged 65 years or older, 40.8% were dissatisfied with their dentures (17). Many do not seek implant-based dentures for several reasons. As in other countries too, the trend of trying the conventional treatment several times can exhaust the public funding and is an indication of a deficient treatment delivery framework.

Patient-driven data can contribute in designing a rational and systematic prognostic strategy to direct the most-suited treatment for different edentulous levels of needs. This would optimize services in the main care setting for edentulous population; that is the primary sector, with no over- or under-provision of care. Moreover, it will distinguish those with extra needs and fit them appropriately with advanced (specialist or multidisciplinary) level of care. This improvement in patient care, provision of equal opportunities, and optimization of scares governmental resources are most needed in current economical crisis.

Additionally, this research will act as a foundation for information needed to analyze costs and benefits in economic evaluation of complete dentures treatment. Long term goals of this research are related to health gain particularly edentulousness related dietary issues.

Chapter Two

Methodology

3 Material and methods

This is a prospective longitudinal observational study carried out in two centres in the Republic of Ireland: Dublin Dental University Hospital (DDUH) and Cork University Dental School and Hospital (CUDSH).

3.1 Patient recruitment

Waiting lists of edentulous patients seeking new conventional complete denture treatment or implant overdenture treatment were obtained from the Department of Restorative Dentistry and Periodontology at both university hospitals. All patients attending for provision of new or replacement dentures, but not immediate complete dentures, were contacted for recruitment.

Inclusion and exclusion criteria were developed. Participants should be:

- Over 18 years old
- Edentulous for at least 3 months
- Self-referred, or referred by a doctor or dentist
- Seeking the provision of dentures (new or replacement)
- Physically well enough to undergo treatment and follow-up
- Able to comprehend the nature of the study and give informed consent

.

Miss Rosaleen Glackin (DDUH) and Miss Vanessa DeVere (CUDSH) were the appointed gatekeepers for this study. Potential participants were contacted by a gatekeeper through mail using a cover letter (Appendix III), information leaflets (Appendix I) and consent form

(Appendix II) before recruitment. Both gatekeepers were not care providers neither were they involved in research project. This method resulted in freedom of participation by potential candidates without unintentional pressure implied by an investigator involved directly in the research or treatment. Participants were recruited from among the dental hospitals' patient populations according to eligibility, inclusion and exclusion criteria. If participants chose to enter the study they were given an appointment with one of the investigators (Dr Sittana Ahmed at DDUH and Dr Seamus Sharkey at CUDSH), who would explain the main points of the study, answer any queries and invite the participant to freely give their written informed consent (Appendix II). The same consent was also countersigned by the investigator once s/he is happy that the participant is fully informed. Confidentiality of personal data of research subjects was always guaranteed. Recruitment continued for 24 months.

Based on a post hoc analysis conducted as part of the first strand of this project (94) to determine the sample size, a target of not less than 52 subjects was considered adequate to obtain statistical power for the OHIP-EDENT and 34 subjects for the total DSQ score. These calculations were based on changes from T1 to T2. In this study a larger sample size was required to allow for comparisons at a third level (T3). A target of 125 was considered adequate taking into considerations possible drop outs and strong patient preferences. A three-monthly monitoring system was used to warrant a sample greatly reflective of the Irish edentate population in regards to the main demographic variables. If no suitable candidates presented for the project, a newspaper advertisement was to be placed to invite edentulous people to participate.

3.2 Ethical approval

Ethical committee approval for this study was obtained from the Health Sciences Faculty Ethics Committee, Trinity College Dublin and University College Cork. The study adhered to the "Declaration of Helsinki" for Ethical Principles for Medical Research Involving Human Subjects (128).

The following forms were approved to be used in the study:

- Study information leaflet (Appendix I)
- Study consent form (Appendix II)
- Letter to prospective participants (Appendix III)
- Information sheet for implant placement (Appendix IV)
- Consent form for implant placement (Appendix V)
- Demographic information sheet (Figure 3-2)
- Questionnaires:

1. Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) (Table 3-2)
2. Oral Health Impact Profile - Edentulous (OHIP-EDENT) (Table 3-3)
3. Denture Satisfaction Questionnaire (DSQ) (Table 3-4)
4. Dental Treatment Uptake Scale (DTUS) (Table 3-5)
5. Life Orientation Test (LOT) (Figure 3-8)

3.3 Data collection and storage

After the inventory questionnaire (Dental Treatment Uptake Scale) was completed and piloted in DDUH in December 2012, the agreed set of questionnaires was assembled in a

research booklet to be used for each patient at the different interview stages of the project. A liaison with data entry company (Seefin Data Management Limited) was made which reviewed the completed questionnaire diaries and assured their data-entry friendly format.

Recruitment of participants began in January 2013 in both DDUH and CUDSH. All precautions were taken to protect the privacy of participants and their confidentiality and to minimize the impact of the research on their physical, mental and social integrity. For data de-identification, each patient was allocated an identification number. This removed personal identifiers from the dataset making it no longer linked with the participant in any way. The one document containing the key identifications for all participants is held in a locked cabinet in the Restorative Department in DDUH with restricted access except to the principal investigator. All computerised data and electronic files were set as security-protected documents with passwords only known to the investigator. The key document that holds the identifier data and the questionnaire booklets are retained locked in a cabinet in the Restorative Department only as long as may be needed for the research's sake and/or until thesis, anticipated publications, and executive summary to the HSE are fully reported and disseminated.

Participation in this study was voluntary. Edentulous research subjects were informed of their right to refuse to participate and right to withdraw to participate at any time without reprisal. The number and reason for drop outs were all documented whenever possible.

3.4 Operation of the study

Regarding timeline and milestones, there were three main strands in the project:

- Strand 1: Observational study of the treatment of edentulous people (0-24 months)
- Strand 2: Surgical implant phase and data collection of implant overdenture participants (12-18 months)
- Strand 3: Analysis and predictive modelling (18-26 months)

The operation of the study is summarized in Figure 3-1 and Table 3-1 below.

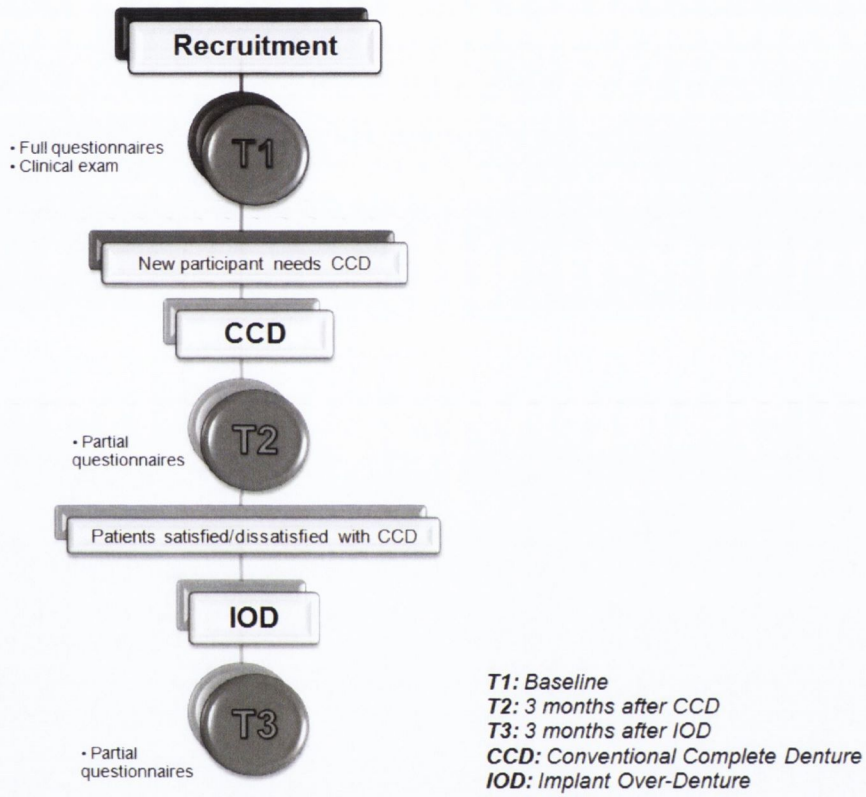


Figure 3-1: Study time/event line

Table 3-1: Summary participant journey

	T1		T2				T3	
	Recruitment and examination	Conventional dentures	3 months post treatment	Offered implant treatment	Implants placed	Overdenture attachment	3 months post treatment	**Total journey** = minimum 11 months
	Data collection		Data collection				Data collection	
Waiting periods	Denture treatment waiting list = variable	Variable = approximately 2 months	3 months waiting time for CD experience	Implant waiting list = variable	Waiting for implant healing = 2 months		3 months waiting time for OD experience	

The principal investigators (Dr Sittana Ahmed and Dr Seamus Sharkey) collected the study data and were not directly involved in providing care. Care providers were either an undergraduate student, post-graduate student, or a clinical hospital staff member. Following consent, investigators arranged for an appointment (maximum 45 minutes) as a pre-treatment assessment at T1 (baseline) before any treatment then again at T2 (3 months after conventional treatment). At the appointment, each participant completed one of the study booklets.

At T2 all patients were provided with implant placement information sheet (Appendix IV) and offered treatment with two small-diameter implants or standard-diameter implants to retain their lower dentures. Standard-diameter implants were offered according to the Dental Hospitals' schedule of fees. Although small-diameter implants were sponsored by ACE Implant Company (ACE Surgical Supply Co. Inc., 1034 Pearl Street, Brockton, MA 02301, U.S.A.), they were offered to participants with a reduced fee to cover the cost of the surgery (€150). This was to prevent bias caused by 'free' treatment that may induce patients to choose unnecessary treatment. Patient-based outcomes may also be biased with free of charge interventions since patients might not have the same appreciation of the true market value of the treatment. In this study, participants were free to choose between regular- and small-diameter implants. Before implant placement, patients were assessed for fitness for implant treatment according to the inclusion/exclusion criteria.

At T3 (3 months after implant treatment), patients were reassessed using the same questionnaires. Only two implants-retained mandibular overdenture treatment was considered in this research.

3.5 Study booklet

The following data were collected in the pre-set study booklet in the same order for each participant:

A. Basic data:

    1. Collection of basic demographic data (Age, sex) - *Non-medical factors*
    2. Health information (major illnesses, medications) - *Global health perceptions*

B. Standardized clinical examination (objective measures) - by the investigator:

    1. Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) (20) - *Biological & Physical factors*

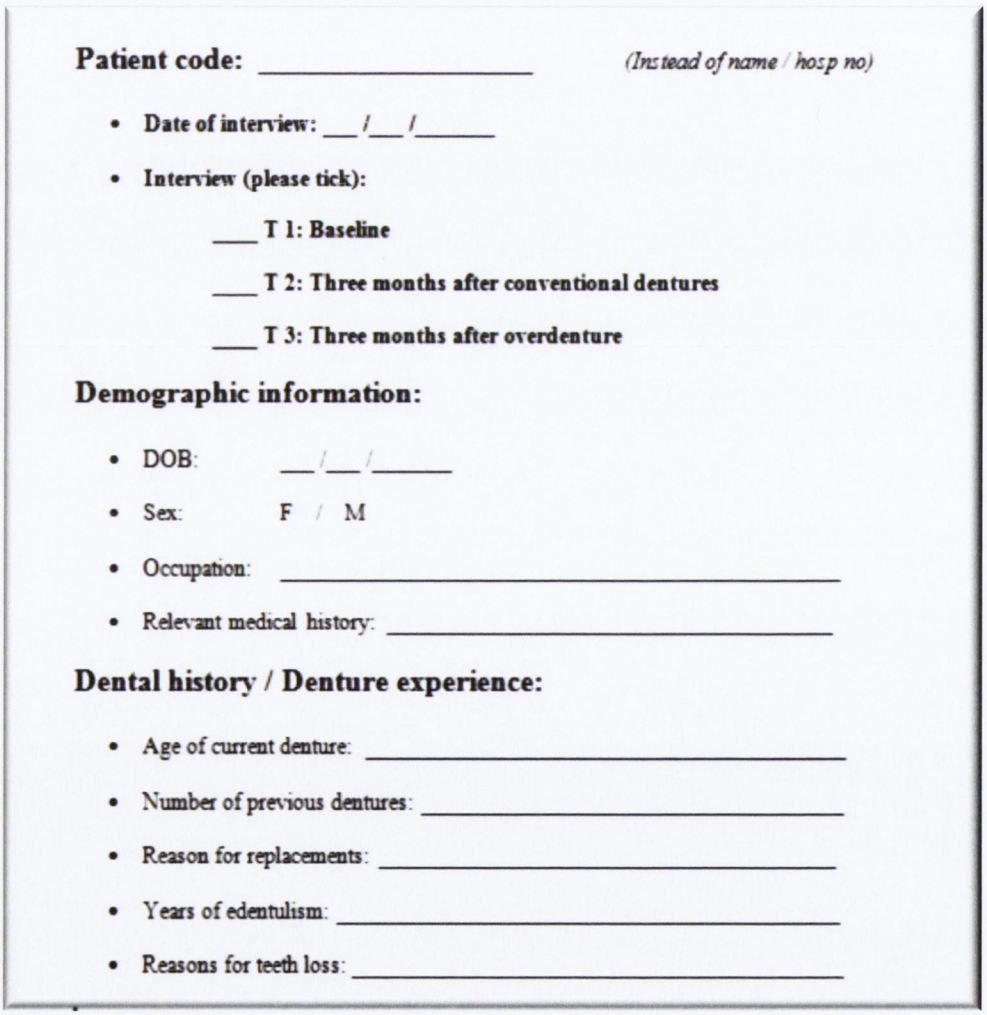
C. Patient-based questionnaires (subjective measures) - by the participant:

    1. Oral Health Impact Profile for Edentulous adults (OHIP-EDENT) (91) - *Functional status / Oral health-related QoL*
    2. Denture Satisfaction Questionnaire (DSQ) (102) - *Symptom status*
    3. Dental Treatment Uptake Scale (DTUS)
    4. Life Orientation Test (LOT) (120)

At T1, the complete set of questionnaires was obtained. At T2 or T3, clinical examination, demographic data, Dental Treatment Uptake Scale, and Life Orientation Test were omitted. The clinical examination took around 5-10 minutes and the questionnaires took around 10-20 minutes. Each questionnaire started with an outline description on how it must be completed. Any further queries were clarified. Questionnaires were completed by participants unassisted.

3.5.1 Demographic data and relevant histories

Figure 3-2 is a copy of the first page of the booklet which included information about interview stage, age, sex (1 = Male, 2= Female), occupation, and medical, dental and denture histories. Occupation was classified according to the International Standard Classification of Occupations (with entries 0 to 9) with additional three more categories: student, housewife, and unemployed. Medical history was classified as: "0 = No relevant medical history", "1 = One relevant medical problem", and "2 = Two or more medical problems". Reasons for teeth loss were categorised into: "1 = Predominately due to caries", "2 = Predominately due to periodontal problems", "3 = Predominately due to trauma", and "4 = Other reasons".



Patient code: _____ *(Instead of name / hosp no)*

- **Date of interview:** ___/___/_____
- **Interview (please tick):**

  ___ **T 1: Baseline**

  ___ **T 2: Three months after conventional dentures**

  ___ **T 3: Three months after overdenture**

Demographic information:

- DOB: ___/___/_____
- Sex: F / M
- Occupation: _____
- Relevant medical history: _____

Dental history / Denture experience:

- Age of current denture: _____
- Number of previous dentures: _____
- Reason for replacements: _____
- Years of edentulism: _____
- Reasons for teeth loss: _____

Figure 3-2: Basic Data

3.5.2 Clinical assessment

The standardized clinical examination was carried out by one of the investigators (qualified, insured dentist) to identify the category of the participant according to the American College of Prosthodontists' Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) (Table 3-2). Using a mouth mirror a non-invasive visual examination of the oral cavity was carried on. Existing radiographs on the records of the patients were viewed to assist classification and assessment of mandibular bone height. Radiographs were not prescribed for the purpose of the checklist. This is in agreement of ALARA (as low as reasonably achievable) principle of radiation. Any necessary adjustments or repair of the prosthesis were carried out. Oral and denture hygiene advice and instructions were given to patients if required.

To increase reliability and reduce inter-examiner disagreement in edentulous patients' clinical examination, a calibration exercise of the research investigators was conducted using ten edentulous patients in November 2012.

3.5.2.1 American College of Prosthodontists' Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE)

PDI-CE (20) shown overleaf in Table 3-2 was used to classify the participants into one of four categories (1 to 4) according to the following parameters:

1. Bone height - Mandibular
2. Residual ridge morphology - Maxilla
3. Muscle attachments-mandibular
4. Maxillo-mandibular relationships

5. Conditions requiring pre-prosthetic surgery
6. Limited inter-arch space
7. Tongue anatomy
8. Modifiers

Table 3-2 Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE)

Checklist for Classification of Complete Edentulism

	Class 1	Class 2	Class 3	Class 4
Bone Height-Mandibular				
21mm or greater				
16-20mm				
11-15mm				
10mm 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 and/post vest, tori, redundant tissue				
Muscle Attachments-Mandibular				
Type A-adequate attached mucosa				
Type B-no b attach mucosa (33-43), +mentalis m				
Type C-no ant b&l vest (33-43), + 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				
18-20mm				
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				

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.*

CLASSIFICATION: _____

Mandibular bone height measurements were recorded in millimetres by a ruler from a panoramic radiograph obtained from the patient's file. If the file was electronic, the digital image was calibrated first to the actual dimensions of the phosphor plate used before digital measurement was carried out. To minimize variability, measurements were made at the section of the mandible with least vertical height (20).

Class I (Figures 3-3 and 3-4) is considered the most favourable with (20):

- Residual mandibular bone height of 21 mm or more.
- Residual maxillary ridge morphology able to resists horizontal/vertical movement of the denture base.
- Muscle attachments located in favourable location assisting in stabilising and retaining denture base
- Class I maxillo-mandibular relationship

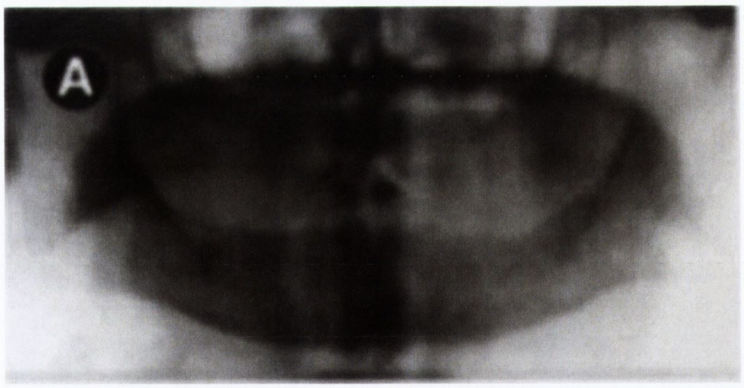


Figure 3-4: Panoramic X-ray of Class I patient

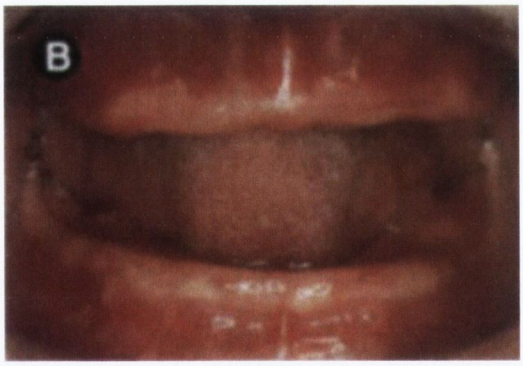


Figure 3-3: Clinical photo of class I patient

Class II (Figure 3-5) is more debilitated in anatomy and characterised by (20):

- Residual bone height of the mandible in the range of 16 to 20 mm
- Maxillary residual ridge morphology that resists horizontal/vertical movement of denture

- Muscle attachments located with limited influence on denture base stability and retention.
- Class I maxillo-mandibular relationship.
- Minor modifiers, psychosocial considerations,
- Mild systemic disease with oral manifestation

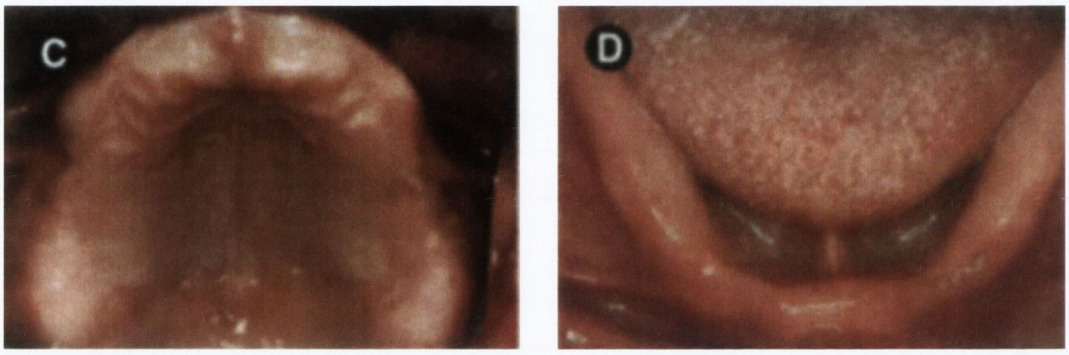


Figure 3-5: Example of class II maxilla and mandible

Class III (Figure 3-6) is worse anatomically than class II with the following features (20):

- 11 to 15 mm is the range of the vertical height of the residual mandibular bone
- In the maxilla, residual ridge morphology minimally resists horizontal/vertical movement of the denture base
- Muscle attachments' location have moderate impact on denture base stability and retention
- Class I, II, or III maxillo-mandibular relationship
- Presence of conditions that require pre-prosthetic surgery:
    - Minor soft tissue procedures
    - Minor hard tissue procedures such as alveoloplasty
    - Simple implant placement without augmentation
    - Multiple extractions leading to complete edentulism and immediate denture
- Limited inter-arch space (18-20 mm)

- Moderate psychosocial consideration and/or moderate oral manifestations of systemic diseases such as xerostomia
- Symptomatic TMD
- Large tongue occluding the interdental space
- Hyperactive gag reflex

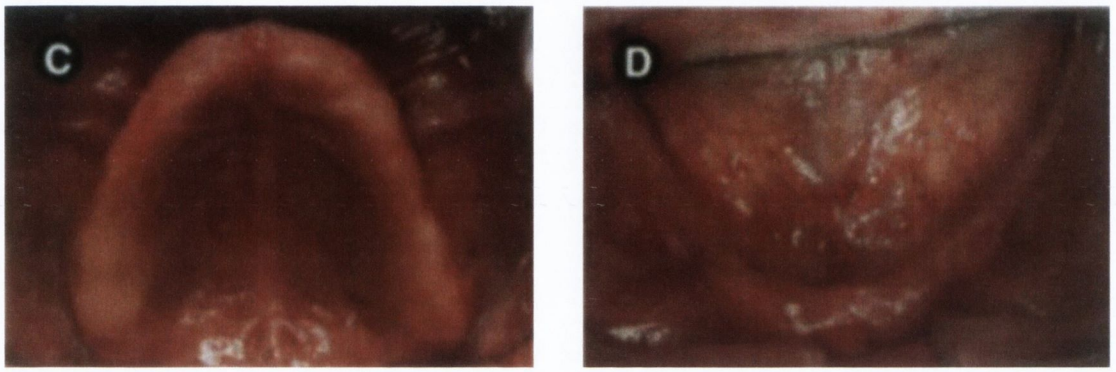


Figure 3-6: Clinical examples of a class III patient

Class IV (Figure 3-7) has the worse anatomic presentation (20):

- Mandibular vertical bone height is reduced to 10 mm or less
- Maxillary residual ridge has no resistance to horizontal/vertical movement
- Location of muscle attachment has significant negative influence on denture base stability and retention
- Class I, II, or III maxillo-mandibular relationships
- Major oral presentations requiring pre-prosthetic surgery:
    - Complex implant placement with augmentation
    - Surgical correction of dento-facial deformities
    - Hard tissue augmentation
- Major soft tissue revision required such as vestibular extensions
- History of paresthesia or dysesthesia.

- Insufficient inter-arch space that requires surgical correction
- Acquired or congenital maxillofacial defects
- Severe oral manifestation of systemic conditions such as complications after oncological treatment
- Maxillo-mandibular incoordination
- Hyperactivity of tongue such as retracted tongue position
- Hyperactive gag reflex managed with medication
- Refractory patient; that is a patient who presents with chronic complaints following appropriate therapy. In denture treatment such patients continue to be unhappy with treatment despite thoroughness of treatment and number of dentures made.
- Psychosocial conditions in need of professional management

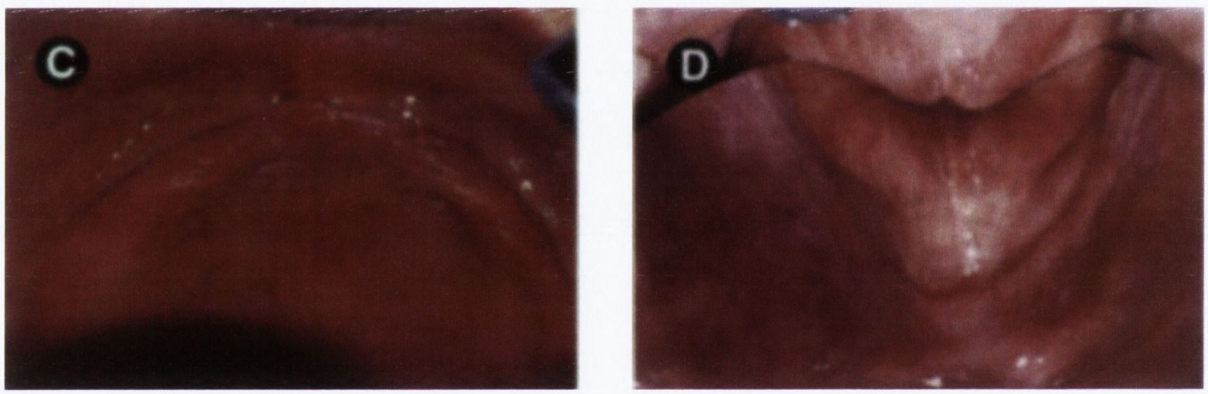


Figure 3-7: Clinical presentation of a Class IV

3.5.3 Questionnaires

3.5.3.1 Oral health Impact Profile

Oral Health Impact Profile - Edentulous (OHIP-EDENT) is a 19-questions scale which is a shortened version of the OHIP-49, yet still containing the same seven domains as its predecessor. It is adopted by Allen and Locker for specific use with edentulous patients (91).

Patients are asked to tick the most appropriate answer against each question, Answers are listed on a 5-point Likert scale format: "0 = Never", "1 = Hardly ever", "2 = Sometimes", "3 = Fairly often", or "4 = Very often". The total score for OHIP-EDENT ranges from 0 to 76. Table 3-3 demonstrates the OHIP-EDENT with its seven domains.

Table 3-3 OHIP-EDENT

ORAL HEALTH IMPACT PROFILE - EDENTULOUS

Please tick the most appropriate answer:

		Very often	*Fairly often*	*Some times*	*Hardly ever*	*Never*
Domain 1: Functional Limitation	1. Have you had difficulty chewing any 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?					
	7. Have you had uncomfortable dentures?					
Domain 3: Psychological Discomfort	8. Have you been worried by dental problems?					
	9. Have you been self-conscious because of your teeth, mouth or dentures?					
Domain 4: Physical Disability	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?					
	12 Have you had to interrupt meals because of problems with your teeth, mouth or dentures?					
Domain 5: Psychological Disability	13. Have you been upset because of problems with your teeth,mouth or dentures?					
	14. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?					
Domain 6: Social Disability	15. Have you avoided going out because of problems with your teeth, mouth or dentures?					
	16. Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures?					
	17. Have you been irritable with other people because of problems with your teeth, mouth or dentures?					
Domain 7: Handicap	18. Have you been unable to enjoy other peoples company as much because of problems with your teeth, mouth or dentures?					
	19. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?					

3.5.3.2 Satisfaction with dentures

The denture satisfaction questionnaire (DSQ) (Table 3-4) used is a modified scale from the one used by Tang et al. (102). The same scale was validated previously in an edentulous Irish population by Harris et al. (93) and Lally et al. (94). The DSQ has eleven items related to mandibular denture satisfaction. It is a Likert-type scale that has different responses in different rating domains. For example, general satisfaction with the mandibular denture is rated on a four point scale: "1=Not satisfied", "2=Neither satisfied nor dissatisfied", "3=Fairly satisfied" and "4=Very satisfied". It is a self-reported questionnaire where participants were asked to choose the phrase that best described their perception at T1, T2 and T3.

The DSQ covers four main Sections:

- DSQ Question 1 (Section 1): Patients' general satisfaction
- Section 2: Physical function (comfort, stability, ability to speak, ability to chew, quality of meals, choice of food),
- Section 3: Psychosocial function (socialization with dentures, denture being a foreign body, and self-confidence), and
- Section 4: general health (general change in life caused by a denture).

Table 3-4 Denture Satisfaction Questionnaire

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 with 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 your 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**

3.5.3.3 Dental treatment uptake scale

A purposive sampling approach, followed by thematic analysis was adopted to develop this scale by Meaney et al. (113) in 2013. Purposive sampling involves targeting a range of patients to represent differing viewpoints which reflect the underlying diversity of a particular condition. A thematic analysis is an inductive method whereby key themes are identified and interpreted (129). The themes that emerge from this quantitative analysis will used to identify items which may be required to indicate those willing be accept of up taking treatment over the other.

Dental Treatment Uptake Scale (DTUS) is a categorical scale (Figure 3-5). On a Likert scale the research subject express how much s/he would agree or disagree about each of the eleven statements. Instructions are printed on the top of the scale explaining that there is no "correct" or "incorrect" answers. DTUS has five possible responses ranging from "1=strongly disagree" to "5=strongly agree". Polarity of statements number 5 and 8 (indicated by (R)) should be reversed before the total DTUS score is calculated based on the sum of the all responses to statements.

Dental Treatment Uptake Scale

Please rate your agreement by ticking the appropriate response.

Be as honest as you can throughout as there are no "correct" or "incorrect" answers.
Answer according to your own thoughts and feelings and try not to let your response to one statement influence your responses to other statements.

Statement	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
If you are not happy with your dentures it makes sense to try a new type of dental treatment					
In the future, I could end up trying new dental treatment					
People who are unhappy with their dentures should consider having these replaced					
If I could have implant treatment for free I would consider having it					
I am happy with my dentures and would not have other types of treatment (R)					
I would think about having dental treatment if I thought it would make me feel better about myself					
If my dentist suggested an improvement to my dentures I would consider having that treatment					
I would never have dental treatment if I thought it would be painful (R)					
If a straight forward dental procedure would improve people's self-image they should think about having it.					
I would seriously consider dental treatment if my dentist recommended it					
If there was a dental treatment that would improve the fit of my lower denture I would think about having it done					

Table 3-5: Dental Treatment Uptake Scale

3.5.3.4 Life Orientation Test

The life Orientation Test (LOT) (Figure 3-8) is a dispositional optimism test associated with extraversion and positive effect (130). It is used in this study to assess the relationship between coping to denture and personality. The LOT was developed by Scheier and Carver in 1985 (120) and became one of the most commonly used optimism tests. The participant are asked to indicate their extent of agreement with 12 statements on a Likert scale ranging from "0 = strongly agree" to "4 = strongly disagree".

Scoring method:

- In order to maintain a consistent polarity of responses for scoring, scores for statements No. 3, 8, 9, and 12 were first reversed (negatively or pessimistically worded statements)
- Statements No. 2, 6, 7 and 10 are filler items and were omitted from total calculation
- Then, items 1, 3, 4, 5, 8, 9, 11, and 12 were summed to obtain the total score

The total score has a possible range of 0 to 32 with high scores indicating a greater degree of optimism. There is no specific criterion to classify an individual as being an optimist or a pessimist. Instead, people vary from very optimistic to very pessimistic, with most being somewhere in the middle (120).

Life Orientation Test (LOT)

Instruction: Please answer the following questions about yourself by indicating the extent of your agreement using the following scale:

[0] = Strongly disagree
[1] = Disagree
[2] = Neutral
[3] = Agree
[4] = Strongly agree

Be as honest and accurate as you can throughout, and try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers.

_____ 1. In uncertain times, I usually expect the best.
_____ 2. It's easy for me to relax.
_____ 3. If something can go wrong for me, it will.
_____ 4. I always look on the bright side of things.
_____ 5. I'm always optimistic about my future.
_____ 6. I enjoy my friends a lot.
_____ 7. It's important for me to keep busy.
_____ 8. I hardly ever expect things to go my way.
_____ 9. Things never work out the way I want them to.
_____ 10. I don't get upset too easily.
_____ 11. I am a believer in the idea that "every cloud has a silver lining."
_____ 12. I rarely count on good things happening to me.

Figure 3-8: Life Orientation Test

3.6 Implant surgery

In April 2013, ACE Surgical Supply Company, Inc© sponsored the study by providing free MiniMark™ surgical kits and implants. MiniMark™ is a one piece (fixture and attachment) Minature dental implant system. It is a small-diameter implant (2.9 mm wide) with Zest LOCATOR® head. It has various lengths. Dr Ioannis Polyzois (DDUH) and Dr Paul Brady (UCC) were the allocated surgeons for implant placement.

3.6.1 Surgical assessment

At T2 appointment; three months after wearing the new prosthesis, participants were invited by the investigator to complete the T2 questionnaire. After that and acknowledging their expressed level of satisfaction with new prosthesis, all patients were offered (Appendix IV):

1. To have no further treatment and to withdraw from the study. The reason for withdrawal and reason for not choosing implant was recorded.
2. To have two regular-platform implants to stabilize mandibular denture, or
3. To have two smaller-platform implants to stabilize mandibular denture

Small-diameter MiniMark implants were offered for free yet the patient still needed to pay a €150 surgical fee. The two regular-platform implants are subject to the standard fees of the dental hospitals. The implant information sheet (Appendix IV), Surgical consent sheet (Appendix V) and Withdrawal sheet (Appendix IV) were presented to the participant. Any queries were answered. If the patient agreed to commit to surgery, an appointment was made with the periodontist for a pre-surgical assessment appointment.

Implant inclusion criteria

In addition to the general inclusion criteria of the study, participants were requested to be:

- Seeking the provision of implant overdentures
- Physically well enough to undergo implant surgery and follow-up
- Able to comprehend the nature of the surgery and give informed consent
- For implant placement, adequate bone quality and quantity is needed for two narrow- or regular-diameter implants intra-foraminally with a minimum length of 10 mm per implant
- At least 1 mm of buccal and lingual cortical bone to remain around the implant

Implant surgery exclusion criteria

Participants were excluded from the study if they do not meet the inclusion criteria and/or specifically participants who:

- have poorly controlled diabetes
- smoke more than 10 cigarettes per day
- are immune compromised
- are at risk of osteochemonecrosis or osteoradionecrosis
- have significant mental illness or personality disorder
- have a history of failed implants
- manifest any other condition that would put them at significant risk of injury or complication

3.6.2 Surgical protocol

Evaluation included a review of patients' medical history, clinical examination, and radiographs where diagnostic images were not already available. The latter may include panoramic X-Ray, lateral cephalogram or CBCT, depending on the clinical indication. The implant surgeon discussed the procedure with each patient and outlined possible alternatives and adverse outcomes. The patient was required to sign a surgical consent form (Appendix V). The fabrication of a surgical guide from the patient's own denture might be prescribed. Each patient received a prophylactic antibiotic (amoxicillin) and a non-steroidal anti-inflammatory at the discretion of the operator.

Procedures were performed under aseptic conditions in an outpatient environment. Under local anaesthesia, with or without sedation, 2.9 mm in diameter implants with treated surfaces were placed, two per patient, in the anterior mandibular zone. The implants had a minimum thread length of 10 mm and a denture attachment (Zest Locator). The mini-implants were inserted approximately at positions 43 and 33, ideally 20 mm apart. Implant placement followed the manufacturer guidelines using a flapless protocol whenever possible and complied with the routine surgical procedures as practiced at the site.

Initial implant stability was assessed by hand testing during the surgery. After insertion, the fitting surface of the mandibular denture was relieved so as not to functionally load the implants. Two months after implant placement, the Locator attachments were fixed to the overdenture intraorally, using self-curing acrylic resin. In order to assess bone levels, radiographs were taken at the time of overdenture loading using a customised X-Ray aiming device (Figure 3-9) made specifically on a surveyor to comply with the paralleling technique

and diminish X-Ray distortion. Post-operative instructions were given to patient as normally practiced by the operator. Analgesics and antibiotics were given as required.

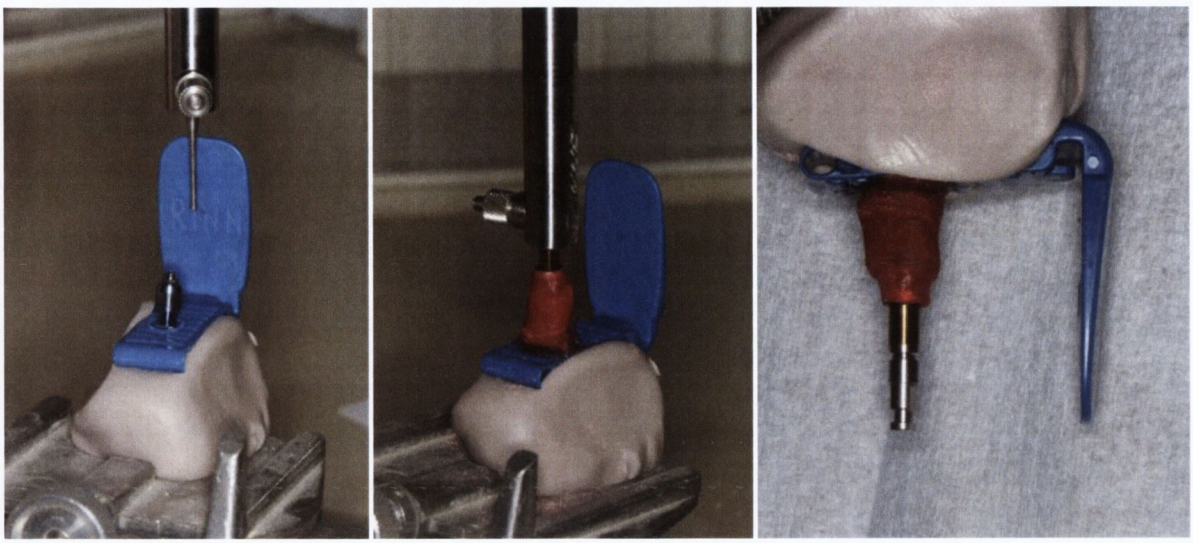


Figure 3-9: X-Rays custom-made aiming device

Patients were contacted by phone within 48 hours of implant placement to check for difficulties or concerns. Each patient had a one week follow up clinical appointment to make sure that healing was progressing as expected, that the implants were secure, and to remove sutures if required. Unless patients had further problems, their next clinical appointments were 8 weeks after surgery to pick-up the Locator attachments to their mandibular denture. After three months they were invited again to fill in the T3 questionnaire.

In the event of implant failure, the implants were to be removed immediately and the site allowed to heal. Another implant would be placed at the site, given the patient consented to the procedure and no other general risk factors are discovered.

4 Statistical analysis

Using the patients' unique identifier, data were recorded in an electronic numeric format (Microsoft Excel Spreadsheet). Statistical analysis of results was done using IBM SPSS® Statistics software version 22 for Windows. The number of individuals that participated in each time point of the study was reported as well as the number and reasons for withdrawal. General descriptive statistics were carried out including frequencies, means and standard deviations for the following:

- Patients' demographic data: age, gender, and occupation
- Relevant medical history
- Denture history: age of current denture, number of previous dentures, years of edentulism, and reasons for teeth loss.

Statistics used to address research questions:

1. To investigate edentulous patients' degree of satisfaction and Oral Health Impact Profile - Edentulous before treatment at baseline (T1), after conventional denture treatment (T2), and then following implant-based treatment (T3)

Plotting and examining data distributions and normality using histograms at T1, T2 and T3 revealed non-normal distribution of the data (chapter three). Hence, comparison of means of the same participant groups but at different timelines was carried out using the non-parametric Wilcoxon signed-ranked test. Calculations were done for total and domain scores for outcome measures OHIP-EDENT and DSQ. Calculations were considered to compare mean changes between T1 to T2, T2 to T3, and T1 to T3. The statistical significance level of p-value was set to 0.05.

2. To classify PDI-CE diagnostic complexity of patients

Descriptive analysis using frequencies, and percentages was carried out to study the different PDI-CE classes of all patients at baseline as well as to study the patients' PDI-CE after sub-grouping according to implant treatment choice and sub-grouping according to state of satisfaction after new conventional denture treatment.

3. To examine the psychological trait of optimism of the participants using Life Orientation Test (LOT)

Reversal of LOT negative statement was carried out and total LOT scores were obtained without consideration to the filter statement. Results were categorized and analysed to assess optimism trends in all patients, implant choice subgroups, and denture satisfaction subgroups after T2.

4. To examine scores of "Dental Treatment Uptake Scale " in the edentulous sample

Similar to LOT, reversal of statements indicated by (R) was carried out and total DTUS scores were calculated. Results were analysed for the overall sample, subgroups according to implant choice decision, and subgroups according to denture satisfaction after T2.

5. To compare those who did choose implant treatment with those who did not and identify characteristics of sub-groups that may indicate treatment choice.

Participants were sub-grouped into two groups: those who did not opt for implant treatment after T2 "No implant group" and those who pursued implant treatment "Implant group". Descriptive data for the two groups were further calculated. Reasons for not choosing implants were also investigated and described. Mean comparison tests were conducted to compare characteristics between the two groups. This allowed examination of factors that explain changes in OHIP-EDENT Total scores at baseline.

6. To investigate groups based on satisfaction and examine baseline key elements of edentulous patients that can indicate satisfaction and success for treatment of edentulism.

After new conventional denture treatment (T2) participants were sub-classified into two groups according to their general denture satisfaction into a "Satisfied group" which included those who reported 'very satisfied' and 'fairly satisfied' with their dentures, and a "Dissatisfied group" which included those who reported being 'not satisfied' with their new dentures. Descriptive analysis of the two groups was done to compare their different characteristics. Further sub-analysis using a mean comparisons tests was conducted in similar fashion to implant choice subgroups analysis.

5 Funding, sponsorship and institutional affiliation

This research was funded by the Health Research Board: grant HRA_HSR/2011/2. ACE Surgical Supply Company, Inc© sponsored the surgical phase of this project.

This is to declare that there are no potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

Chapter Three

Results

6 Results

6.1 Descriptive statistics

125 participants were recruited to this study at baseline, 85 (68%) from DDUH and 40 (32%) from CUH. There were 41 men (33%) and 84 women (67%), with mean age of 69.9 years (*SD* = 10.84) and age range of 30 to 91 years (Tables 6-1, 2). All 125 completed the T1 interview including a full set of questionnaires and clinical examination.

Table 6-1: Demographic and denture history data descriptive statistics at baseline (T1)

	Range	Minimum	Maximum	Mean	Std. Deviation
Patient Age	61	30	91	69.85	10.838
Age of current denture	60.5	.5	61.0	12.492	12.8804
Number of previous dentures	10	0	10	2.92	1.880
Years of edentulism	70.0	.0	70.0	31.028	20.6842

Table 6-2: Patient gender

	Frequency	Percent
Male	41	32.8
Female	84	67.2
Total	125	100.0

Three months after wearing new conventional dentures, 112 participants continued in the study and completed T2 questionnaires. Thirteen dropped out for various reasons: 3 deceased, 1 changed address, 2 withdrew from the study, 1 sought treatment elsewhere, and 6 did not complete their conventional denture treatment. After T2, 21 participants chose to have implant treatment when offered but only 12 completed T3 questionnaires. This is because: 5 were waiting for implant surgery, 1 was in the post-surgical healing phase, and 3 did not finish the three month period of overdenture wearing. One hundred and one participants did not consider implants for reasons discussed later. Of the 24 small-diameter implants placed,

none failed throughout the research observation period. Figure 6-1 shows the flowchart and number of participants in different stages of the study.

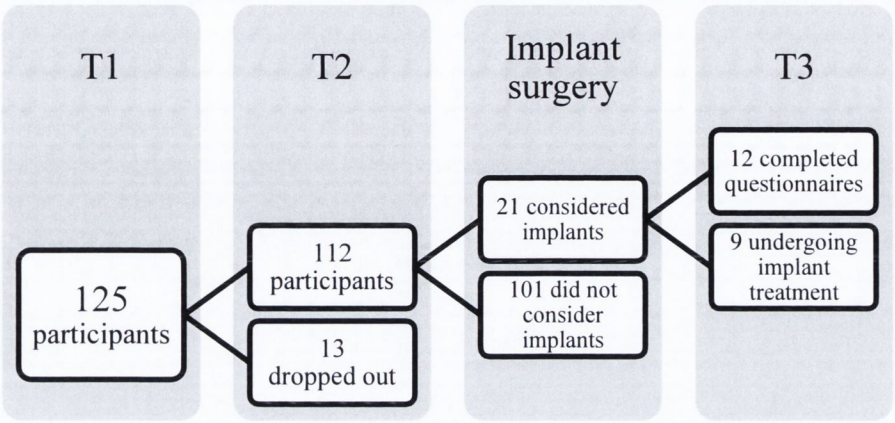


Figure 6-1: Flow chart of participants

Table 6-1 also contains descriptive statistics about patients' denture history. The age of dentures at presentation was on average 12.5 years with a range of 0.5 to 60.5 years, while the mean number of previous dentures was 3, with some participants having no previous denture and others having up to 10 previous dentures. The average time since a participant became edentulous was 31 years (SD = 20.7). Frequencies and percentages of age of denture at presentation, number of previous dentures and years of edentulism are further reported according to different categorical intervals in Figures 6-2, 6-3 and 6-4 respectively. Reasons for tooth loss are given in Figure 6-5; caries was the most common reason.

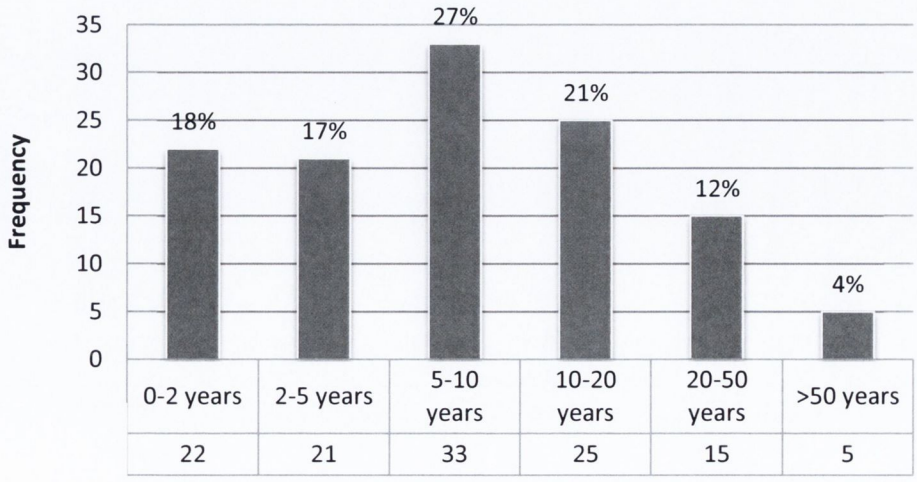


Figure 6-2: Age of denture at T1

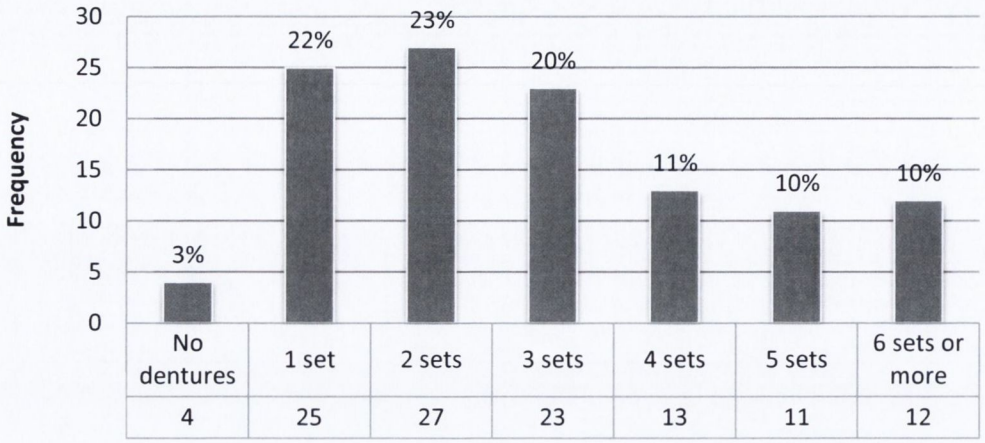


Figure 6-3: Number of previous dentures at T1

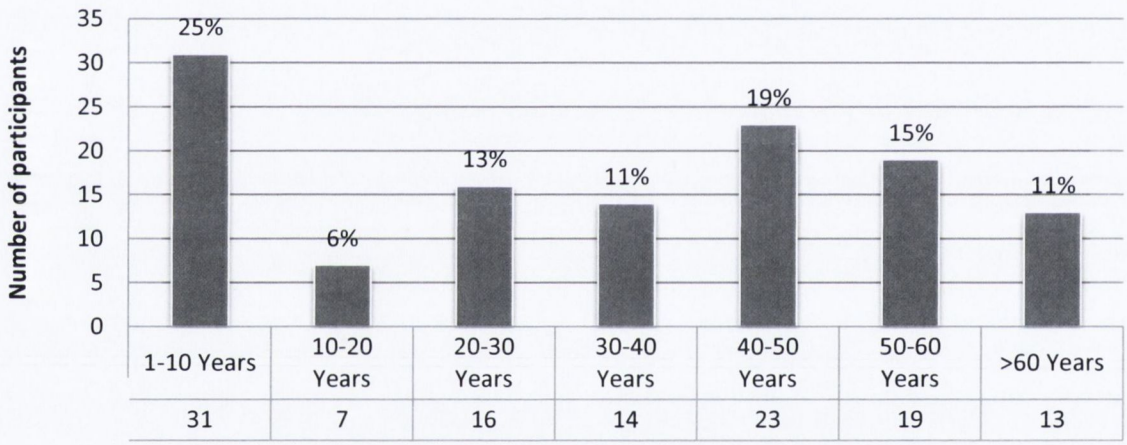


Figure 6-4: Years of edentulism at T1

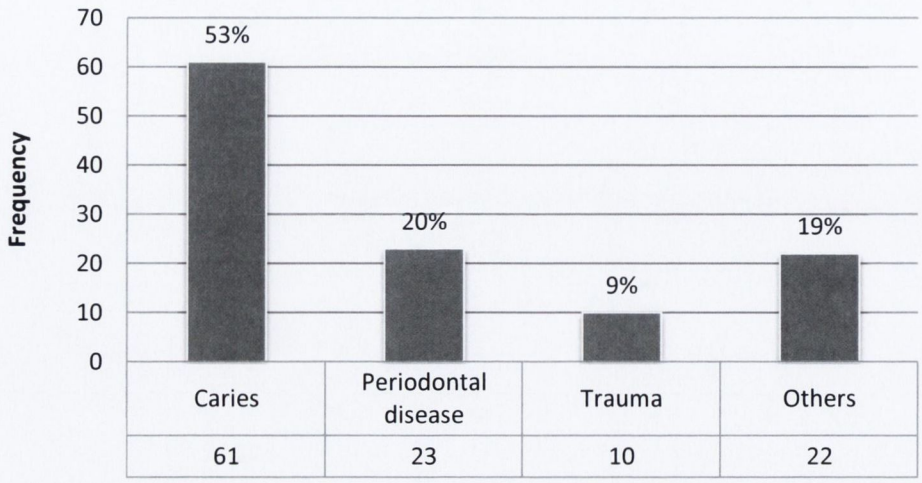


Figure 6-5: Reasons for tooth loss

The breakdown of participants according to their relevant medical history and occupation is shown below in Figure 6-6 and Table 6-3. Over half of the patients had one or more relevant medical conditions and almost one quarter were unemployed or housewives.

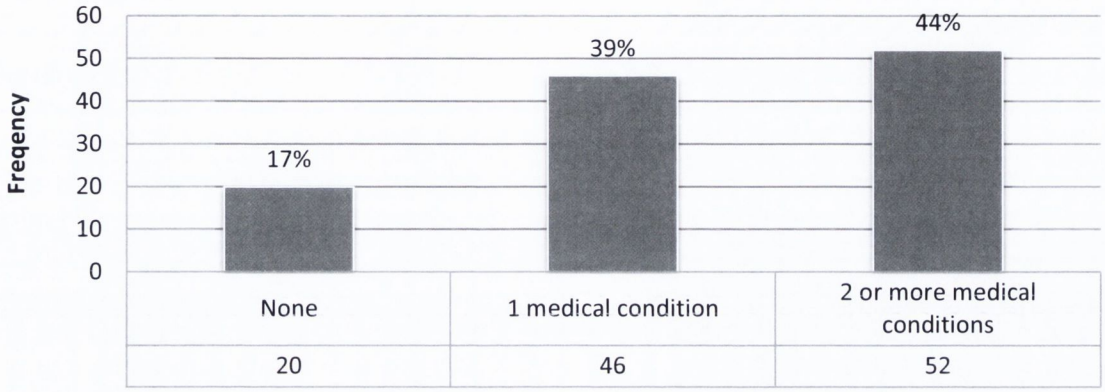


Figure 6-6: Relevant medical history

Table 6-3: Patient Occupation

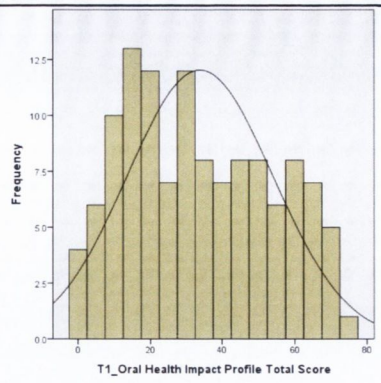
Occupation groups	Frequency	Percent
Armed forces occupations	1	.8
Professionals	12	9.6
Technicians and associate professionals	14	11.2
Clerical support workers	3	2.4
Service and sales workers	11	8.8
Skilled agricultural, forestry and fishery workers	3	2.4
Craft and related trades workers	9	7.2
Plant and machine operators, and assemblers	3	2.4
Elementary occupations	6	4.8
Unemployed	30	24.0

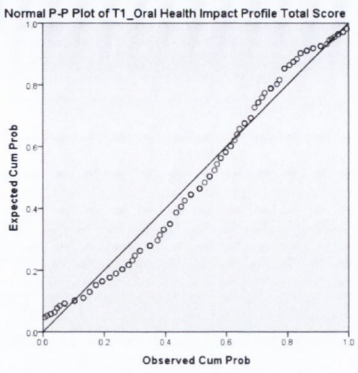
6.2 Investigation of edentulous patients' degree of satisfaction and Oral Health Impact Profile at T1, T2, and T3

Both histograms and corresponding P-P plots (probability-probability plot) in Figures 6-7 and 6-8 were used to examine the data's distribution and assess normality for outcome measures for Denture Satisfaction Questionnaire (DSQ) and Oral Health Impact Profile for Edentulous (OHIP-EDENT) total scores. This allowed proper selection of statistical tests. None of the histograms followed a normal distribution with graphs being even more skewed at T2 and T3. Skewness values were positive (towards the left) for OHIP-EDENT and negative (towards the right) for DSQ. This suggests that by T2 and T3, OHIP-EDENT scores were much more clustered around the lower end of the scale and those of DSQ were more clustered towards the higher end of the scale when compared to T1 data distribution. The skew occurs because of the positive treatment effect of the new conventional dentures in T2 and implant-retained overdentures in T3 captured by the outcome measures. The P-P plots echo the histograms' distribution since data points did not fall very close to the ideal diagonal line. Due to the non-normal distribution, non-parametric test methods (Wilcoxon signed ranked test and Mann-Whitney test) were used to compare mean differences in outcome measures.

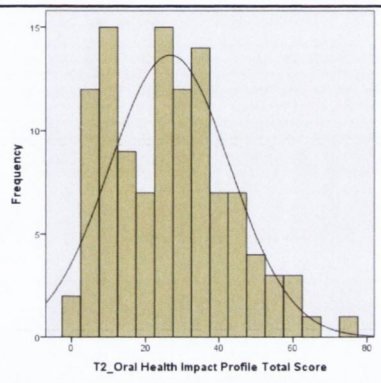
Figure 6-7: Histograms (left) and P-P plots* (right) of OHIP-EDENT Total score over the 3 time points (T1, T2, T3)

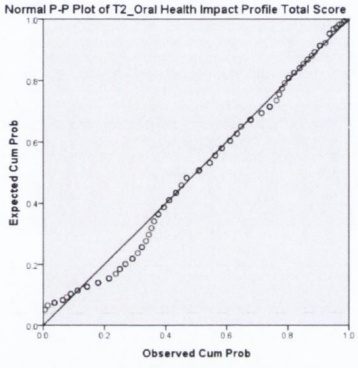
T1





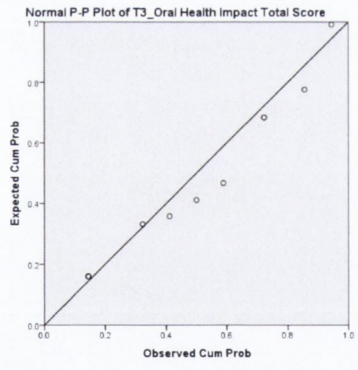
T2





T3

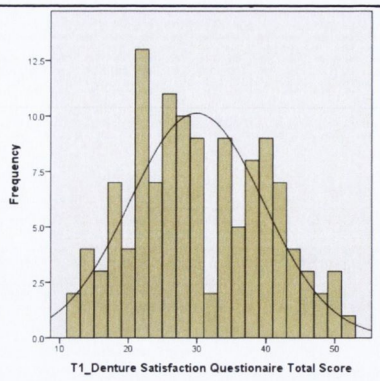


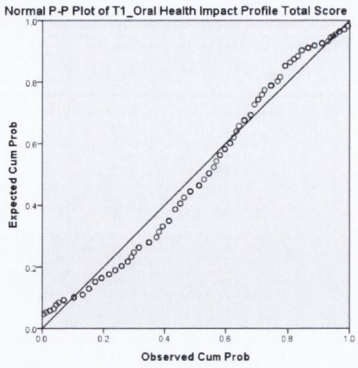


** The observed cumulative probability (Observed Cum Prob) of OHIP-EDENT Total score is plotted against the expected cumulative probability (Expected Cum Prob) of a normal distribution in the P-P plots*

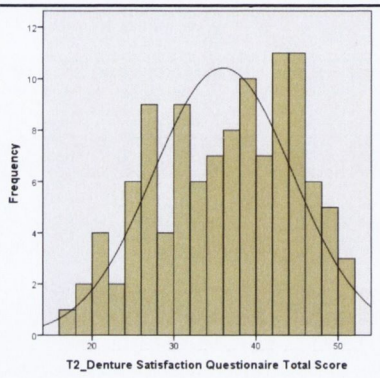
Figure 6-8: Histograms (left) and P-P plots* (right) of DSQ Total score over the 3 time points (T1, T2, T3)

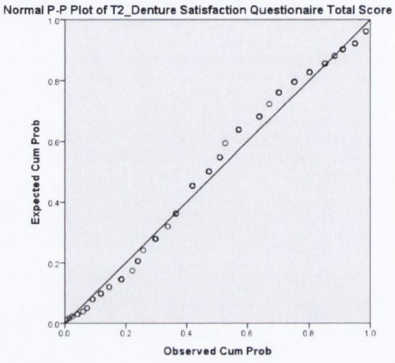
T1



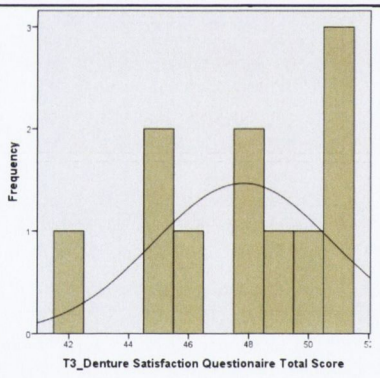


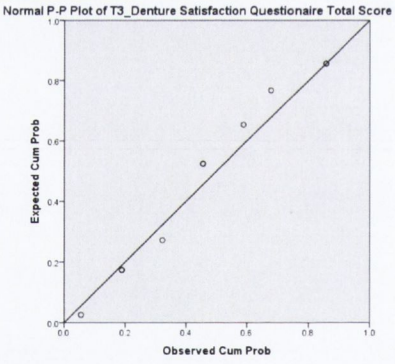
T2





T3





** The observed cumulative probability (Observed Cum Prob) of DSQ Total score is plotted against the expected cumulative probability (Expected Cum Prob) of a normal distribution in the P-P plots*

Descriptive data with mean values and standard deviations of the following outcome variables: OHIP-EDENT Total, OHIP-EDENT Domains, DSQ Total, and General satisfaction scores (DSQ Question 1), are presented in Tables 6-4 and 6-5 for baseline (T1), after wearing conventional dentures (T2) and after wearing implant-retained prosthesis (T3). There was an increase in mean scores from T1 to T2 and a further increase from T2 to T3 in DSQ scores. The opposite was seen with OHIP-EDENT scores.

Table 6-4: Descriptive data for Denture satisfaction questionnaire (DSQ) Total scores and DSQ Question 1 at each time point

Parameter \ Statistics		Number	Range	Minimum	Maximum	Mean	Standard Deviation
DSQ Total score	T1	123	39	12	51	29.91	9.69
	T2	111	34	17	51	35.97	8.50
	T3	11	9	42	51	47.82	2.99
General denture satisfaction score (Question 1)	T1	124	3	1	4	1.98	1.10
	T2	112	3	1	4	2.62	1.12
	T3	12	1	3	4	3.75	0.45

Table 6-5: Descriptive data for OHIP-DENT total and domain scores for each time point

Parameter \ Statistics		Number	Range	Minimum	Maximum	Mean	Standard Deviation
OHIP-EDENT Total score	T1	122	76	0	76	33.81	20.21
	T2	112	75	0	75	26.71	16.37
	T3	11	48	0	48	14.18	14.26
OHIP-EDENT Domain 1 (Functional Limitation)	T1	124	12	0	12	7.73	3.63
	T2	112	12	0	12	5.98	3.26
	T3	11	7	0	7	3.36	2.73
OHIP-EDENT Domain 2 (Physical Pain)	T1	124	16	0	16	8.48	4.74
	T2	112	16	0	16	7.13	4.26
	T3	11	8	0	8	3.45	3.01
OHIP-EDENT Domain 3 (Psychological Discomfort)	T1	125	8	0	8	3.43	2.67
	T2	112	8	0	8	2.58	2.31
	T3	11	8	0	8	1.27	2.45
OHIP-EDENT Domain 4 (Physical Disability)	T1	124	12	0	12	5.94	4.10
	T2	112	12	0	12	5.32	3.65
	T3	11	10	0	10	2.73	3.52
OHIP-EDENT Domain 5 (Psychological Disability)	T1	124	8	0	8	3.31	2.93
	T2	112	8	0	8	2.21	2.35
	T3	11	4	0	4	1.27	1.42
OHIP-EDENT Domain 6 (Social Disability)	T1	123	12	0	12	2.41	3.05
	T2	112	12	0	12	1.74	2.45
	T3	11	4	0	4	1.09	1.64
OHIP-EDENT Domain 7 (Handicap)	T1	123	8	0	8	2.30	2.62
	T2	112	8	0	8	1.74	2.18
	T3	11	8	0	8	1.00	2.37

The Wilcoxon signed-ranked test was used to compare the differences in mean scores of outcome measures at different time points, that is; compare repeated measures within the same participants' group. For the following analysis the conventional 0.05 significance level of *p*-value was set as the critical value. When *p*-values were less than 0.05 (indicated with*), the null hypothesis was rejected and the difference between the two means was considered statistically significant.

For DSQ, Table 6-6 demonstrates that whenever total DSQ and DSQ Question 1 mean scores were compared between any two time-points, the *p*-values fell below the 0.05 significance value. The Wilcoxon signed-rank test detected a highly statistical significance difference when the implant overdenture group (T3) was compared, although it had 12 participants.

Table 6-6: Wilcoxon signed-rank test p-values for DSQ scale

Time-line changes / Parameter	*p*-value for mean score difference		
	from **T1 to T2**	from **T2 to T3**	from **T1 to T3**
DSQ Total score	$p < 0.001$*	$p < 0.01$*	$p < 0.01$*
General denture satisfaction score (Question 1)	$p < 0.001$*	$p = 0.01$*	$p < 0.01$*

Results of the Wilcoxon signed-rank test comparing differences in OHIP-EDENT total and its seven domains are shown in Table 6-7. Most of the *p*-values were less than 0.05 allowing rejection of the null hypothesis that there is no difference in OHIP scores between treatment intervals. This was true except for domain 4 (Physical Disability) between T1 and T2, domain 6 (Social Disability) between T1 and T3, and domains 5 and 6 between T2 and T3 where *p*-values were above 0.05 and null hypothesis was not rejected. Although the implant group consisted of 12 participants (T3), the tests were statistically significant for changes in OHIP-EDENT mean scores of this group except for domains 6 and 5.

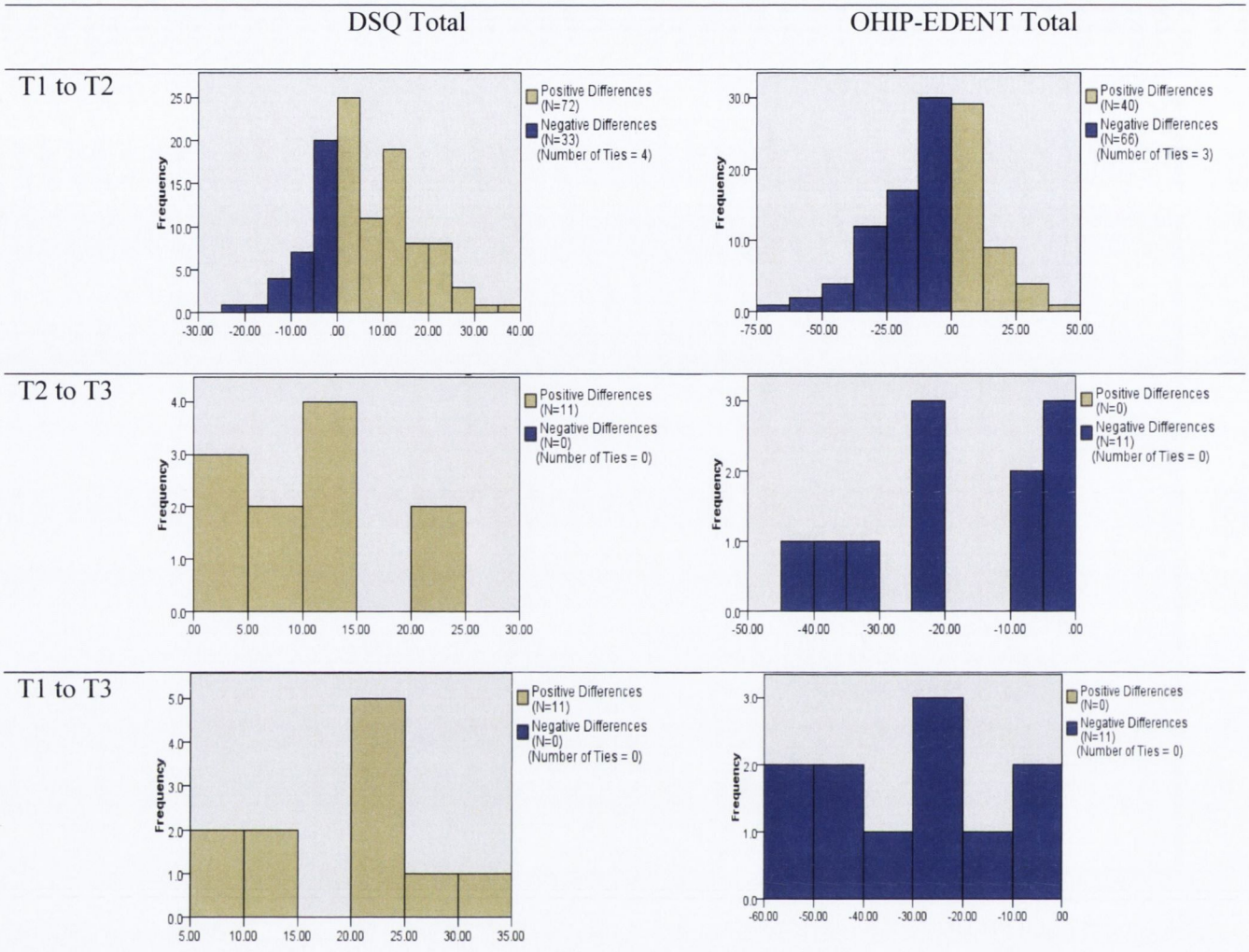
Table 6-7: Wilcoxon signed-rank test p-values for OHIP-EDENT scale

Time-line changes / Parameter	*p*-value for mean score difference		
	from **T1 to T2**	from **T2 to T3**	from **T1 to T3**
OHIP-EDENT Total score	$p = 0.001$*	$p < 0.01$*	$p < 0.01$*
OHIP-EDENT Domain 1 (Functional Limitation)	$p = 0.001$*	$p < 0.01$*	$p < 0.01$*
OHIP-EDENT Domain 2 (Physical Pain)	$p = 0.001$*	$p < 0.01$*	$p < 0.01$*
OHIP-EDENT Domain 3 (Psychological Discomfort)	$p = 0.001$*	$p < 0.01$*	$p < 0.01$*
OHIP-EDENT Domain 4 (Physical Disability)	$p = 0.41$	$p = 0.02$*	$p < 0.01$*
OHIP-EDENT Domain 5 (Psychological Disability)	$p < 0.001$*	$p = 0.11$	$p < 0.01$*
OHIP-EDENT Domain 6 (Social Disability)	$p < 0.03$*	$p = 0.17$	$p = 0.09$
OHIP-EDENT Domain 7 (Handicap)	$p = 0.04$*	$p = 0.01$*	$p = 0.01$*

To understand further the differences in outcome measure means, histograms of the distribution of differences are presented in Figure 6-9 where yellow and blue bars represent positive and negative differences, respectively. Being an impact scale, an improvement in outcome is reflected by a decrease in OHIP-EDENT scores after treatment and the situation is reversed for DSQ levels. For the group that received new conventional dentures (T1 to T2) despite having different coloured bars, the majority of participants exhibited positive changes (more yellow bars) in DSQ levels, whereas more patients predominately showed negative changes (more blue bars) in OHIP-EDENT scores. Moreover, after the experience of wearing implant overdentures (T2 to T3, or T1 to T3), all the DSQ scale bars were yellow (positive changes) and all the OHIP-EDENT scale bars were blue (negative changes) reflecting a positive improvement in denture wearing experience in both scales for all patients.

Figure 6-9: Distribution of mean differences for DSQ Total score (left) and OHIP-EDENT Total Score (right) between intervals T1-T2, T2-T3, T1-T3

(Axis X represents the differences in scores between intervals, Axis Y represents the number of participants)



6.3 Examination of the PDI-CE diagnostic complexity of patients

To assess whether the Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) classification was used consistently by both clinical investigators (Sittana Ahmed and Seamus Sharkey), an intra-class correlation (ICC) analysis was used as a quantitative measure of reliability. After reviewing McGarry et al. (20) classification guidelines, the two clinical investigators carried out an inter-examiner calibration task by examining the same 11 patients separately. Table 6-8 reveals a statistically significant high ICC (above 0.9)

indicating an excellent inter-examiner reliability and a consistency in using the PDI-CE classification.

Table 6-8: Intraclass Correlation Coefficient for inter-rater reliability and reproducibility of PDI-CE

		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation[b]	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.946[a]	.822	.985	36.200	10	10	.000
Average Measures	.972[c]	.903	.992	36.200	10	10	.000

A breakdown of frequencies and percentages of each PDI class is presented in Figure 6-10. Over two thirds (68%) of the participants at baseline fell into the two most severe classes; III and IV.

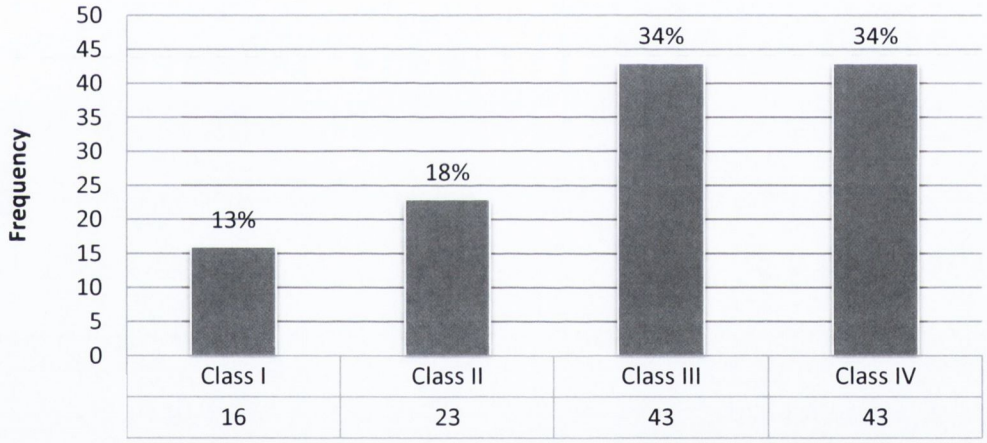


Figure 6-10: PDI-CE Classification at T1

Participants were further sub-classified as those who chose to have implant treatment (n=21) and those who did not (n=102) to examine PDI-CE in different patient categories (Table 6-9). Similar trends to the whole sample were seen; that is, two thirds of participants fell in Class III or IV.

Table 6-9: PDI-CE Classification in implant choice subgroups

Patient's Implant Choice		Frequency	Percentage	
Did not choose implants	Class I	15	14.7	31.4
	Class II	17	16.7	
	Class III	37	36.3	68.7
	Class IV	33	32.4	
	Total	102	100.0	
Chose implants	Class I	1	4.8	28.6
	Class II	5	23.8	
	Class III	5	23.8	71.4
	Class IV	10	47.6	
	Total	21	100.0	

Another sub-grouping of the patients was done according to patients' reported level of satisfaction. Based on their answer to the General Denture Satisfaction question (DSQ Question 1) three months after the provision of new conventional denture at T2, participants were grouped into a "Satisfied" group (those who reported being highly or fairly satisfied at T2), or a "Dissatisfied" group (those who reported being not satisfied at T2). PDI-CE classification for the two subgroups is shown in Table 6-10. Although the two subgroups had comparable trends to those of the whole population and to the PDI-CE classifications subgroups, it was interesting to see that there were more patients classified as Class III or IV (67%) in the "Satisfied" group than in the "Dissatisfied" group (61%).

Table 6-10: PDI-CE Classification according to satisfaction groups

General denture satisfaction at T2		Frequency	Percentage	
Dissatisfied at T2	Class I	6	20.7	37.9
	Class II	5	17.2	
	Class III	6	20.7	62.1
	Class IV	12	41.4	
	Total	29	100.0	
Satisfied at T2	Class I	9	10.7	32.1
	Class II	18	21.4	
	Class III	31	36.9	67.9
	Class IV	26	31.0	
	Total	84	100.0	

6.4 Investigation of the psychological trait of optimism of the participants using the Life Orientation Test

The scoring system of Scheier and Carver (120) was followed to obtain total LOT scores for each patient. General descriptive statistics of LOT scores (Mean = 20) are reported in Table 6-11. Although it is difficult to indicate a clear cut off point for high and low optimism traits, total scores were categorized into three groups to facilitate explanation of the results. These groups had scores of (0 to 11), (12 to 22) and (23 to 32) to describe lower, average and higher optimism scores respectively. Most (59%, n=69) participants fell in the middle range while only a few (6%, n=7) reported lower LOT scores. Thirty four percent of patients (n=40) demonstrated higher optimism scores (Figure 6-11).

Table 6-11: Descriptive Statistics for LOT at baseline

	Range	Minimum	Maximum	Mean	Std. Deviation
Life Orientation Test	32	0	32	20	5.58

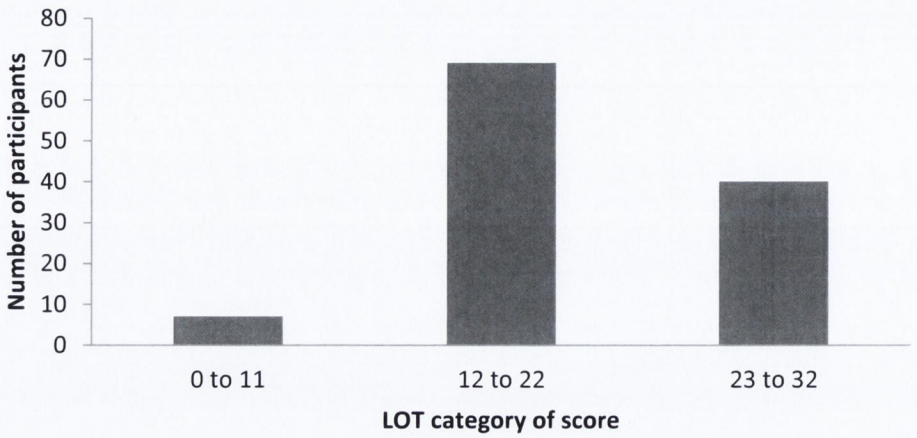


Figure 6-11: Frequencies of LOT according to categories

In order to look for possible associations in the data, patients were split in a similar fashion to the subgrouping system used in the PDI-CE analysis above; that is, according to patients' implant choice and general denture satisfaction. Descriptive statistics for LOT are shown in Table 6-12. In the sub-classification groups, the differences in average scores of LOT were small and ranged from 19.2 to 20.8. Since those comparisons were between two groups differing from each other on the variable, the Mann-Whitney test was used as the non-parametric equivalent of the independent *t*-test to test mean differences. The *p*-values were 0.19 and 0.43 when testing the differences between LOT scores in the subgroups based on implant choice and general denture satisfaction at T2, respectively.

Table 6-12: LOT total scores according to implant treatment choice and General satisfaction subgroups

Patient's Implant Choice		N	Range	Minimum	Maximum	Mean	Std. Deviation
Did not choose implants	LOT Total Score	93	32	0	32	20.54	5.738
Chose implants	LOT Total Score	21	22	7	29	19.24	4.560
General denture satisfaction at T2							
Dissatisfied at T2	LOT Total Score	29	30	0	30	19.03	6.327
Satisfied at T2	LOT Total Score	75	25	7	32	20.83	5.134

6.5 Examination of "Dental Treatment Uptake Scale" scores in edentulous subgroups

Means, standard deviations and ranges of DTUS for all patients (Table 6-13) and subgroups were calculated (Tables 6-14). The Mann-Whitney test was used to compare mean scores differences of DTUS between subgroups. Those who chose to have implants at T3 reported statistically significant (p = 0.01) higher levels of DTUS at baseline when compared to the "Did not choose implant" group (41.6 vs. 46.2). Further, when comparing "Satisfied" and "Dissatisfied" groups, the latter reported statistically significant (p = 0.04) higher baseline DTUS mean scores (44.7 vs. 41.5).

Table 6-13: Descriptive Statistics for DTUS at baseline

	N	Range	Minimum	Maximum	Mean	Std. Deviation
T1 Dental Treatment Uptake Scale Total Score	114	39	16	55	42.39	7.006

Table 6-14: DTUS total scores according to implant treatment choice and General satisfaction subgroups

Patient's Implant Choice		N	Range	Minimum	Maximum	Mean	Std. Deviation
Did not choose implants	DTUS Total Score	91	39	16	55	41.64	7.080
Chose implants	DTUS Total Score	21	19	35	54	46.24	5.309
General denture satisfaction at T2							
Dissatisfied at T2	DTUS Total Score	29	27	28	55	44.69	6.57
Satisfied at T2	DTUS Total Score	73	39	16	55	41.53	6.86

6.6 Comparison of groups based on implant choice, examining characteristics that may indicate treatment choice

After dividing participants according to implant choice into "Chose implant" group (n=21) and "Did not choose implant" group (n=102), descriptive data for the two groups were

calculated to investigate groups' baseline characteristics (Tables 6-15 and 6-16). Although the male:female ratio was slightly increased in the group who chose implant treatment, the number of females dominated in both groups. Average number of previous dentures and years of edentulism were comparable in the subgroups ($p = 0.87$). There was a statistically significant difference ($p < 0.05$) between the mean age of those who "Chose implants" and those who "Did not choose implants" where the latter were younger. Age of denture at presentation was 14 years on average for those who chose implants and 5 years for those who chose not to have implant treatment and this difference was found to be statistically significant ($p < 0.05$). All the above comparisons were tested using the Mann-Whitney test.

Table 6-15: Patient gender based on implant choice

Patient's Implant Choice		Frequency	Percent
Did not choose implants	Male	32	31.4
	Female	70	68.6
	Total	102	100.0
Chose implants	Male	9	42.9
	Female	12	57.1
	Total	21	100.0

Table 6-16: Descriptive Statistics for participants based on their implant treatment choice

Patient's Implant Choice		Minimum	Maximum	Mean	Std. Deviation
Did not choose implants	Patient Age	30	91	70.8	10.62
	Age of current denture	0.5	61	13.9	13.63
	Number of previous dentures	0	10	2.9	1.85
	Years of edentulism	0	70	31.0	21.00
Chose implants	Patient Age	39	80	64.6	10.52
	Age of current denture	1	12	5.1	3.10
	Number of previous dentures	0	8	3.1	2.09
	Years of edentulism	2	60	29.8	19.67

Table 6-17 lists General denture satisfaction (DSQ Question 1) at baseline for different implant choice groups at T1, T2, and T3. The "Chose implants" group reported slightly less General Denture satisfaction scores (DSQ Question 1) at both research points T1 and T2,

when compared to those "Did not choose implant" group but these differences were not statistically significant (Table 6-18). Although only 11 patients completed T3, they reported the highest General Denture satisfaction scores (DSQ Question 1) of any group at T3.

Table 6-17: General denture satisfaction (DSQ Question 1) for different implant choice groups T1, T2, and T3

Patient's Implant Choice		N	Minimum	Maximum	Mean	Std. Deviation
Did not choose implant	T1 General Denture Satisfaction	101	1	4	2.03	1.118
	T2 General Denture Satisfaction	89	1	4	2.67	1.106
Chose implants	T1 General Denture Satisfaction	21	1	4	1.71	1.007
	T2 General Denture Satisfaction	21	1	4	2.45	1.224
	T3 General Denture Satisfaction	12	3	4	3.75	0.452

Table 6-18: Whitney Mann test for DSQ Question 1 mean differences for different implant choice groups

Whitney Mann test	T1 General Denture Satisfaction	T2 General Denture Satisfaction
p-value of mean differences between "Did not choose implants" and "Chose implants"	0.31	0.47

Table 6-19 looks at total DSQ among implant choice groups while Table 6-20 shows the Mann-Whitney test for mean differences between those groups. Changes in total DSQ followed the same path as previous changes of General Denture Satisfaction (DSQ Question 1).

Table 6-19: Total DSQ T1, T2 and T3 for different implant choice groups

Patient's Implant Choice		N	Minimum	Maximum	Mean	Std. Deviation
Did not choose implants	T1 DSQ Total Score	100	12	50	30.19	9.84
	T2 DSQ Total Score	88	19	51	36.81	8.29
Chose implants	T1 DSQ Total Score	21	13	51	28.38	9.27
	T2 DSQ Total Score	21	17	48	33.14	9.04
	T3 DSQ Total Score	11	42	51	47.82	2.99

Table 6-20: Mann-Whitney test for DSQ Total score mean differences for different implant choice groups

Whitney Mann test	T1 DSQ Total Score	T2 DSQ Total Score
p-value of mean differences between "Did not choose implants" and "Chose implants"	0.55	0.07

Mean OHIP-EDENT total scores at the different time points are listed in Table 6-21 and followed similar trends to those of the DSQ. The group of patients who went on to have implants had a higher mean OHIP-EDENT scores at both baseline (T1) and 3 months after new dentures provision (T2) compared to scores of those who chose not have implants placed. Mean differences tested using the Mann-Whitney test between T1 and T2 were statistically significant (Table 6-22). However, the sample size is small for the "Chose implant" cohort (n=21). It is interesting to see that those who chose to have implants did not report a minimum score of "0" at either T1 or T2 while this occurred for the "did not have implant group".

Table 6-21: Distribution of OHIP scores at T1, T2, and T3 for the implant choice groups

Patient's Implant Choice		N	Minimum	Maximum	Mean	Std. Deviation
Did not choose implants	T1 OHIP-EDENT Total Score	99	0	76	31.87	20.49
	T2 OHIP-EDENT Total Score	89	0	75	25.00	16.07
Chose implants	T1 OHIP-EDENT Total Score	21	8	70	43.90	16.60
	T2 OHIP-EDENT Total Score	21	3	62	34.57	16.26
	T3 OHIP-EDENT Total Score	11	0	48	14.18	14.26

Table 6-22: Mann-Whitney test for mean differences in OHIP-EDENT Total score for implant choice groups

Whitney Mann test	T1 OHIP-EDENT Total Score	T2 OHIP-EDENT Total Score
p-value of mean differences between "Did not choose implants" and "Chose implants"	0.02	0.02

Table 6-23 provides the breakdown of the OHIP-EDENT in both implant choice groups at different time points.

Table 6-23: OHIP-EDENT domain scores at T1, T2, and T3 for the implant choice groups

Patient's Implant Choice		N	Minimum	Maximum	Mean	Std. Deviation
Did not have	T1 OHIP-EDENT Domain 1	101	0	12	7.44	3.634
	T1 OHIP-EDENT Domain 2	101	0	16	8.10	4.822
	T1 OHIP-EDENT Domain 3	102	0	8	3.11	2.594
	T1 OHIP-EDENT Domain 4	101	0	12	5.53	4.117
	T1 OHIP-EDENT Domain 5	101	0	8	3.09	2.970
	T1 OHIP-EDENT Domain 6	100	0	12	2.27	3.097
	T1 OHIP-EDENT Domain 7	100	0	8	2.11	2.617
	T2 OHIP-EDENT Domain 1	89	0	12	5.60	3.154
	T2 OHIP-EDENT Domain 2	89	0	16	6.80	4.165
	T2 OHIP-EDENT Domain 3	89	0	8	2.39	2.234
	T2 OHIP-EDENT Domain 4	89	0	12	4.90	3.590
	T2 OHIP-EDENT Domain 5	89	0	8	2.15	2.328
	T2 OHIP-EDENT Domain 6	89	0	12	1.62	2.538
	T2 OHIP-EDENT Domain 7	89	0	8	1.55	2.164
Had implants	T1 OHIP-EDENT Domain 1	21	2	12	9.24	3.419
	T1 OHIP-EDENT Domain 2	21	4	16	10.52	3.881
	T1 OHIP-EDENT Domain 3	21	0	8	5.05	2.578
	T1 OHIP-EDENT Domain 4	21	0	12	8.05	3.514
	T1 OHIP-EDENT Domain 5	21	0	8	4.52	2.562
	T1 OHIP-EDENT Domain 6	21	0	9	3.14	2.886
	T1 OHIP-EDENT Domain 7	21	0	8	3.38	2.500
	T2 OHIP-EDENT Domain 1	21	2	12	7.57	3.385
	T2 OHIP-EDENT Domain 2	21	0	15	8.71	4.540
	T2 OHIP-EDENT Domain 3	21	0	8	3.52	2.482
	T2 OHIP-EDENT Domain 4	21	0	12	7.29	3.379
	T2 OHIP-EDENT Domain 5	21	0	8	2.67	2.477
	T2 OHIP-EDENT Domain 6	21	0	8	2.24	2.143
	T2 OHIP-EDENT Domain 7	21	0	8	2.57	2.226
	T3 OHIP-EDENT Domain 1	11	0	7	3.36	2.730
	T3 OHIP-EDENT Domain 2	11	0	8	3.45	3.012
	T3 OHIP-EDENT Domain 3	11	0	8	1.27	2.453
	T3 OHIP-EDENT Domain 4	11	0	10	2.73	3.524
	T3 OHIP-EDENT Domain 5	11	0	4	1.27	1.421
	T3 OHIP-EDENT Domain 6	11	0	4	1.09	1.640
	T3 OHIP-EDENT Domain 7	11	0	8	1.00	2.366

To investigate further characteristics that may indicate treatment choice, participants who did not consider implant treatment after the provision of new dentures at T2 were asked directly what were their reasons for declining implant treatment. Their answers were listed in Table 6-24 where satisfaction with new dentures (45%) and fear of surgery (26%) ranked the two main reasons.

Table 6-24: Reason for not pursuing implant treatment in the "Did not choose implants" group

Patient's Implant Choice		Frequency	Percent
Did not choose implants	Cost of implants	9	11.1
	Time it takes for implant treatment	1	1.2
	To avoid surgical treatment	21	25.9
	Satisfied with dentures	36	44.4
	Osteoporosis	3	3.7
	Age	4	4.9
	Unable to provide consent	1	1.2
	Illness	1	1.2
	Deceased	5	6.2

Table 6-25 looked at distribution of implant choice groups when patients were asked whether they would consider implant treatment at no cost. There were 71 patient who agreed with the fourth statement of DTUS "If I could have implant treatment for free I would consider having it", yet 74.6% (n=53) of them refused implant treatment when offered to them for a minimal fee. Table 6-26 explores their reasons for refusal which confirms that minimal cost (€150) was not a main contributing barrier.

Table 6-25: Distribution of those who agreed on DTUS question 4 "If I could have implant treatment for free I would consider having it" based on implant choice

Patient's Implant Choice	Frequency	Percent
Did not choose implants	53	74.6
Chose implants	18	25.4

Table 6-26: Reason for Withdrawal for those who agreed on DTUS question 4 yet did not choose implant treatment

		Frequency	Valid Percent
Valid	Cost of implants	4	8.9
	Time it takes for implant treatment	1	2.2
	To avoid surgical treatment	12	26.7
	Satisfied with dentures	22	48.9
	Osteoporosis	3	6.7
	Age	1	2.2
	Unable to provide consent	1	2.2
	Deceased	1	2.2

6.7 Investigation of groups based on satisfaction and examination of baseline characteristics of edentulous patients that can indicate satisfaction and treatment success

Participants after new conventional denture treatment were sub-classified into two groups that represent the two extremes of general denture satisfaction: a "Satisfied group" which combines those who were very satisfied and fairly satisfied with their dentures after T2 (n=83), and a "Dissatisfied group" which includes those were not satisfied (n=29). Those who reported "Neutral" satisfaction at T2 were not considered in the comparison. Figure 6-12 demonstrates the flow of the two groups with respect to their implant choice and Tables 6-27 and 6-28 show the comparison of their characteristics. Approximately two thirds (62.1-65.5%) were females. The mean age of "Dissatisfied" patients (Mean =67 years) was younger than that of "Satisfied" group (Mean =71 years) with $p = 0.05$. The age of denture at baseline was less for dissatisfied groups (9.96 vs. 12.78) but this was not statistically significant ($p = 0.53$). The average number of previous dentures and time since a participant was edentulous were alike in sub-groups and differences were not statistically significant. These mean comparisons were conducted using the Mann-Whitney test.

Table 6-27: Patient gender according to satisfaction groups

T2 Satisfaction Groups		Frequency	Percent
Dissatisfied	Male	11	37.9
	Female	18	62.1
	Total	29	100.0
Satisfied	Male	29	34.5
	Female	55	65.5
	Total	84	100.0

Table 6-28: Descriptive Statistics for participants based on their general satisfaction at T2

T2 Satisfaction Groups		Minimum	Maximum	Mean	Std. Deviation
Dissatisfied	Patient Age	47	90	67.28	10.60
	Age of current denture	1.0	55	9.96	11.42
	Number of previous dentures	0	8	2.96	1.95
	Years of edentulism	1.0	70	30.29	20.76
Satisfied	Patient Age	39	91	71.12	10.21
	Age of current denture	0.5	61	12.78	13.44
	Number of previous dentures	0	8	2.83	1.73
	Years of edentulism	0	68.	30.55	20.58

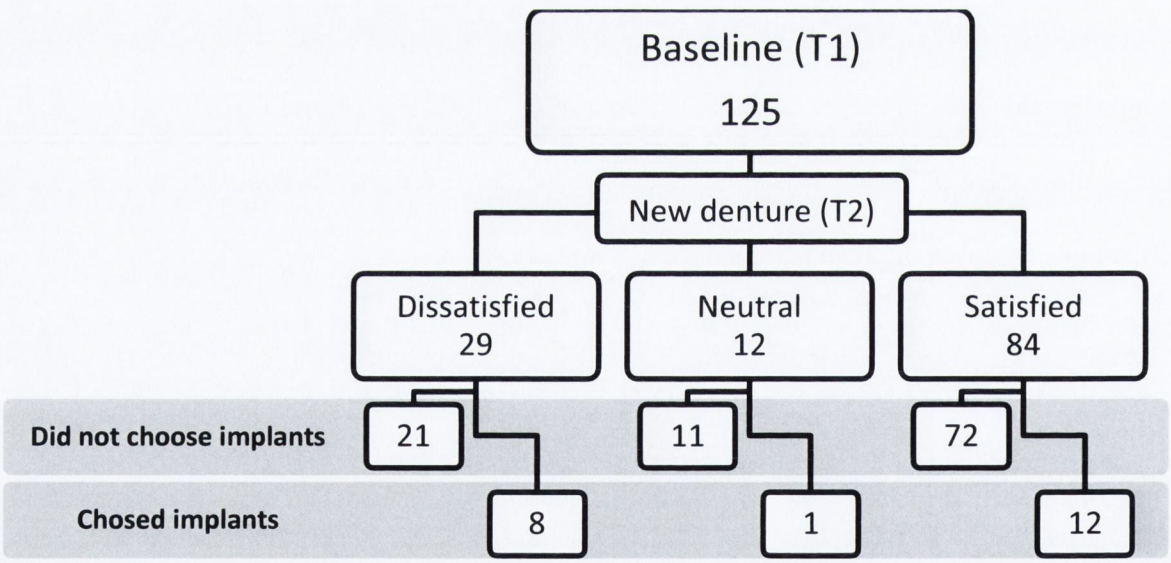


Figure 6-12: Flowchart of patients' general denture satisfaction and implant choice

Figure 6-12 shows that many (n=21) who were not satisfied with their new dentures after T2 refused to pursue implant treatment, while some (n=12) who were satisfied with their new dentures considered implant treatment. Table 6-29 analyses further the reasons that the

dissatisfied majority did not consider implant treatment. 50% reported "to avoid surgical treatment" was their reason for withdrawal.

Table 6-29: Reasons for not choosing implant treatment in satisfaction subgroups

T2 Satisfaction Groups		Frequency	Percent
Dissatisfied	Cost of implants	1	5.6
	Time it takes for implant treatment	1	5.6
	To avoid surgical treatment	9	50.0
	Satisfied with dentures	3	16.7
	Osteoporosis	1	5.6
	Age	1	5.6
	Unable to provide consent	1	5.6
	Deceased	1	5.6
Satisfied	Cost of implants	5	8.6
	To avoid surgical treatment	11	19.0
	Satisfied with dentures	33	56.9
	Osteoporosis	2	3.4
	Age	2	3.4
	Illness	1	1.7
	Deceased	4	6.9

Table 6-30 provides responses of satisfaction subgroups to DTUS question number 8 "I would never have dental treatment if I thought it would be painful". Sixty two percent of the dissatisfied participants agreed or strongly agreed with the statement.

Table 6-30: Responses of DTUS question number 8 "I would never have dental treatment if I thought it would be painful" in satisfaction subgroups

T2 Satisfaction Groups		Frequency	Percent
Dissatisfied	Strongly disagree	4	13.8
	Disagree	3	10.3
	Neither agree or disagree	4	13.8
	Agree	13	44.8
	Strongly agree	5	17.2
Satisfied	Strongly disagree	7	9.5
	Disagree	17	23.0
	Neither agree or disagree	17	23.0
	Agree	24	32.4
	Strongly agree	9	12.2

Table 6-31 show the breakdown of those who "agreed and strongly agreed" on the DTUS number 4 statement "If I could have implant treatment for free I would consider having it" among the different satisfaction groups and Table 6-32 describes the reasons for refusing implants in those subgroups. Twenty two of the "Dissatisfied" participants agreed to have implant treatment for free if offered, yet 50% of them reported "to avoid surgery" was their reason to not opt for implant treatment when it was offered for minimal fees. Seventeen percent answered that they were satisfied with their dentures although they fell in the dissatisfied group.

Table 6-31: Satisfaction groups who agreed on DTUS statement 4 "If I could have implant treatment for free I would consider having it"

	Frequency	Percent
Dissatisfied	22	33.8
Satisfied	43	66.2

Table 6-32: Reasons for refusing implant treatment for "Dissatisfied" participants who agreed on DTUS statement number 4

	Frequency	Percent
Cost of implants	1	8.3
Time it takes for implant treatment	1	8.3
To avoid surgical treatment	6	50.0
Satisfied with dentures	2	16.7
Osteoporosis	1	8.3
Unable to provide consent	1	8.3

Table 6-33 describes the General denture satisfaction (DSQ Question 1) and Table 6-34 reports the *p*-values of their mean differences. Means in General Denture Satisfaction (DSQ Question 1) were found to be statistically significant between different satisfaction groups at both T1 and T2 stages, with those in the “Dissatisfied” group having lower baseline and T2 satisfaction values.

Table 6-33: General denture satisfaction (DSQ Question 1) for different satisfaction sub-groups

Patient's General Satisfaction at T2		N	Minimum	Maximum	Mean	Std. Deviation
Dissatisfied	T1 General Denture Satisfaction	29	1	4	1.38	.775
	T2 General Denture Satisfaction	28	1	1	1.00	.000
	T3 General Denture Satisfaction	2	3	4	3.50	.707
Satisfied	T1 General Denture Satisfaction	83	1	4	2.16	1.153
	T2 General Denture Satisfaction	71	3	4	3.39	.492
	T3 General Denture Satisfaction	9	3	4	3.89	.333

Table 6-34: Mann-Whitney test for DSQ Question 1 mean differences for different general satisfaction groups

Whitney Mann test	T1 General Denture Satisfaction	T2 General Denture Satisfaction
p-value of mean differences between "Dissatisfied" and " Satisfied"	$p = 0.002$	$p < 0.001$

Table 6-35 lists the total DSQ for different general satisfaction groups. Similar findings were found with DSQ Total scores to those of the DSQ Question 1 and they were also found to be statistically significant (Table 6-36)

Table 6-35: Total DSQ for different general satisfaction groups

Patient's General Satisfaction at T2		N	Minimum	Maximum	Mean	Std. Deviation
Dissatisfied	T1 DSQ Total Score	29	12	38	24.72	6.755
	T2 DSQ Total Score	28	17	48	27.21	7.115
	T3 DSQ Total Score	2	42	49	45.50	4.950
Satisfied	T1 DSQ Total Score	83	12	51	31.18	9.953
	T2 DSQ Total Score	71	27	51	40.20	5.845
	T3 DSQ Total Score	8	45	51	48.63	2.560

Table 6-36: Mann-Whitney test for DSQ Total score mean differences for satisfaction sub-groups

Whitney Mann test	T1 DSQ Total Score	T2 DSQ Total Score
p-value of mean differences between "Dissatisfied" and " Satisfied"	$p < 0.003$	$p < 0.001$

Similarly, the different trends of OHIP-EDENT total scores were investigated between "Dissatisfied" and "Satisfied" groups in Table 6-37. Dissatisfied participants at T1 and T2

had statistically significant much higher baseline OHIP-EDENT Total scores than those who were satisfied (44.07 vs. 31.35). Mann-Whitney test *p*-values are shown in table 6-38.

Table 6-37: Distribution of OHIP scores at T1, T2, and T3 for satisfaction sub-groups

Patient's General Satisfaction at T2		N	Minimum	Maximum	Mean	Std. Deviation
Dissatisfied	T1 OHIP-EDENT Total Score	29	7	72	44.07	19.719
	T2 OHIP-EDENT Total Score	28	22	75	40.11	12.276
Satisfied	T1 OHIP-EDENT Total Score	81	0	76	31.35	19.880
	T2 OHIP-EDENT Total Score	72	0	67	20.72	14.906
	T3 OHIP-EDENT Total Score	11	0	48	14.18	14.26

Table 6-38: Whitney Mann test for OHIP-EDENT Total score mean differences for satisfaction sub-groups

Whitney Mann test	T1 OHIP-EDENT Total Score	T2 OHIP-EDENT Total Score
p-value of mean differences between "Dissatisfied" and " Satisfied"	$p = 0.006$	$p < 0.001$

Chapter Four

Discussion

7 Discussion

7.1 General aspects

Some literature suggests a consensus that IODs are superior to CCDs for the treatment of patients with an edentulous mandible (14, 15). There is lack of evidence regarding how much different edentulous individuals would gain from IODs since patients have different clinical presentations, backgrounds, limitations, expectations and preferences (35, 110). This bi-centred prospective longitudinal study aimed generally to identify edentulous sub-groups with characteristics that relate to satisfaction and success of conventional complete dentures and two-implant overdentures. This is through examining prospectively several attributes in an edentulous cohort (anatomic complexity, psychological trait of optimism, dental treatment uptake profile, baseline denture satisfaction and OHRQoL) and relates them to different patients' categories. This study also provided a better understanding of edentulous patients' treatment choices and decision-making in relation to conventional and complex denture treatment. To our knowledge, this is the first study on this topic, in which the predictive value of patient-based questionnaire was examined to identify characteristics of edentulous patients that can indicate treatment choices and/or satisfaction.

Especially in the current tight economic circumstances, public funding has become more and more scarce and must be targeted towards eligible patients most likely to gain from treatment. In edentulism, this should be implemented by targeting resources toward subjects who are not satisfied with being edentulous and have poor OHRQoL status (35). Unfortunately this is not a simple equation where factors are known and easy to control; in fact, the problem is amplified by many factors. With edentulism, a cure is not the objective of treatment but instead the reduction in morbidity caused by the disability. The impact of edentulism on QoL

is highly variable among individuals as well as time-dependent, consequently the impact of corresponding interventions will vary (96, 131). Newer approaches in research incorporated in this study that amalgamate subjective and objective measures may provide better understanding in the management of edentulism (131).

There were many reasons for choosing the design of the current study primarily bearing in mind that the aim was to investigate patient characteristics in relation to treatment choices and satisfaction, rather than measuring a treatment effect:

- Most investigations have concentrated on one form of investigation. In this project, a wide range of tests (objective and subjective measures) were applied to assess different aspects of edentulous patients.
- Unlike some studies, the assessment of edentulous patients was extended beyond conventional treatment experience to include implant-based treatment.
- This study examines genuine patient preferences for treatment without allocation to different treatment options by the investigators. The former approach allows for an exploration of treatment choices among edentulous patients while the latter is used to determine the intervention's treatment effect. Previous studies have shown that treatment preferences can be a high risk for bias in clinical trials. For example, some patients felt disappointed, or even withdrew from studies, when they were randomised into a group that did not match their particular interests and this subsequently impacted on their outcome ratings (97, 109, 110, 132). Some participants wanted implant treatment after conventional treatment in a CCD group (133), while others declined implants when they were randomized to an IOD group (110). As much as these finding are disturbing and confusing, they are also interesting and arouse curiosity to understand patients' preferences. Feine et al. (132) presented a review

with proposed clinical trial designs, along with the differences between them. These designs do not apply to this project since their purpose is to study the effect of treatment preferences on a new therapy that has not been tested.

- Although randomized controlled trials (RCTs) are considered the "gold standard" in the assessment of treatment effectiveness, they can be susceptible to bias. This is because edentulism is a chronic condition in nature and its management is considered a palliative treatment, hence intervention aims to improve function, QoL and satisfaction. This is better assessed through patient-centred outcomes and therefore double-blinding is not possible. Also, patients cannot be blinded to implant treatment in a classic stringent RCT, hence implant studies in edentulism cannot meet the "gold standard" as they lack the double-blinding quality (35, 132). Furthermore, RCTs usually set careful inclusion and exclusion criteria to obtain a filtered study sample, which will be treated within controlled centres of clinical excellence. This too may compromise the external validity of the study; that is, the ability to generalize the results to other patients (62). Also, RCTs provide little information about patients' actual preference due to the randomized nature of the study. Patients who volunteer for a RCT may not represent those who have intense treatment preferences, for reasons of their own (134).
- Unlike cross-sectional and retrospective designs, prospective studies are well-suited since they are true longitudinal studies that can examine outcome measures before and after intervention and can explore trends in treatment choices, patient preferences and satisfaction.

7.2 Basic data descriptive analysis

This study consisted of edentulous subjects who were referred to Dublin or Cork Dental Hospitals to seek denture treatment. The mean age of the sample represented an elderly population (Mean=69.9) (Table 6-1). This is expected since tooth loss is strongly associated with age (13) and since multiple dentures are expected to be required during an edentulous patient's life. Similar to national (17) and international (10) demographics, there were more edentulous females in our sample than males (male:female ratio of 1:2) (Table 6-2). In Ireland, this might be attributed to the traditional practice of edentulating young women when they experienced dental problems. Eighty three percent of the sample had one or more significant medical conditions (Figure 6-6). According to the 2000/02 national survey "Oral Health of Irish Adults" (17), adults with systemic disease had higher levels of edentulism than those without systemic disease. In agreement with other reviews (9, 12), the two main etiologic factors associated with edentulism were caries (53%) and periodontal disease (20%), while trauma (9%) and other causes (19%) were less reported (Table 6-5).

From T1 to T2, thirteen subjects (10.4%) withdrew from the study (Figure 6-1). This relatively small drop-out percentage is acceptable given the age and mobility of the cohort sample and was comparable to other studies (135, 136). The low withdrawal proportion is probably attributed to investigators' special care in patient follow up, flexibility in appointments, and participants' education about the importance of research involvement.

From T2 to T3, nine patients were still waiting to complete implant treatment by the time thesis was written. Delaying factors that made the patient's journey very long, in many instances exceeding one year, included: timely denture fabrication as part of treatment by students in a dental school setting, denture and implant surgery waiting lists, and the 3-

months post-treatment evaluation times. By T2, only 21 (16.8%) subjects consented for implant treatment when it was offered for minimal charges. Likewise, Walton et al. (54) found that more than one third (36%) of recruits were averse to an offer of implants at no cost to stabilize their CCDs. This is one of the most intriguing results in this study where a very low percentage of people accepted what is considered a "high-priced, high-class treatment"; that is, the implant retained-overdenture over conventional intervention. The high percentage of refusals decreased sample size in the implant group and could influence the validity of the study results, hence results related to implant group must be interpreted with caution. A high percentage of implant treatment rejection has been noted previously and puzzled several investigators (54, 110). They emphasized the need for studies that address questions directly related to individuals' true values and priorities.

Some investigators have advocated a 6 to 9 year period as a reasonable denture lifetime after which mechanical wear and tear and ridge resorption will be evident (137). More recently it was advocated to replace dentures at shorter intervals (5 years) to eliminate pathogenic denture biofilm (9). Patients have tendency to use their dentures well beyond their normal expected lifetime (137). In this study one participant wore his dentures for 60 years and 64% wore theirs beyond the recommended denture replacement period (Figure 6-2). On the other hand, 18% of patients had dentures for less than two years and sought replacement; this could be because this study did not exclude immediate denture wearers. The mean number of previous dentures was three denture sets, which is less than the desired given that the average period of edentulousness was 31 years.

7.3 Investigation of edentulous patients' degree of satisfaction and Oral Health Impact Profile for Edentulous at T1, T2, and T3

Ratings for both denture satisfaction and OHIP have been widely used as an assessment of edentulous patient status and of treatment outcome. Although they measure different entities, a highly significant relationship between denture satisfaction and OHIP has been established in the literature (96). An accumulating body of scientific evidence has emerged in the past two decades examining treatment efficiency of CCDs and IODs in edentulous mandibles. Two systematic reviews (35, 42) and several randomized control trials (93, 97, 108-110, 135, 138, 139) substantiated the positive impact of both interventions on patient satisfaction and OHRQoL. They also confirmed that more improvement of both measures is seen with implant overdentures compared with their conventional counterparts. In this study similar trends and treatment efficacy were captured by both DSQ and OHIP-EDENT instruments There was a consistent statistically significant ($p \leq 0.01$) increase in the post-treatment DSQ mean scores (total or question 1) throughout treatment stages (Tables 6-4 and 6-6), indicating gain in denture satisfaction levels. A similar picture was seen in OHRQoL where a progressive decrease in the negative impact of OHIP-EDENT scores (total or domains) throughout the research timelines was observed (Table 6-5). OHIP-EDENT is an impact scale; therefore, a reduction in the scale indicates an improvement in the outcome due to decreased impact on the participant's life following the provision of a new denture or overdenture. Table 6-7 shows that these improvements of the OHIP-EDENT domains were statistically significant ($p < 0.05$) in most comparisons (20 out of 24). Hence, the null hypothesis that there is there is no difference in denture satisfaction or OHIP scores post-treatment was rejected. These results provide additional data to the existing evidence affirming the superiority of mandibular IOD and supporting the McGill and York consensus

statements (14, 15). It is noteworthy that T3 group was small in size, yet mean comparison test were still able to detect statistically significant improvement in outcome measures.

The above findings confirmed that our sample had an adequate size since statistical tests displayed enough power in treatment effect analysis after each intervention. The results also confirmed that the selection of the outcome measures used in this study (DSQ and OHIP-EDENT) was appropriate since they reliably captured the expected changes in comparable fashion to other studies. Effect size analysis was not part of this dissertation since it was conducted in a proceeding strand of this project (94) using the same edentulous cohort.

In the current study, participants were interviewed at baseline (T1), 3 months after CCDs (T2) and 3 months after IODs (T3). A Study design with interviews at 3 months after intervention was advocated by others (93) since it provided an adequate adjustment period and prosthesis experience for assessment of function, QoL and satisfaction. Patients were not informed about an implant treatment option until they completed the second set of questionnaires, 3-months after treatment with CCDs (T2). This was necessary to avoid any unintentional bias related favouring in response for a specific treatment option.

Harris et al. (93) advocated the fabrication of newly CCDs (T2 time line in this study) to decrease degree of variability since data at baseline (T1) would be based on different nature of complaints of patients' original dentures which were worn for variable lengths of time. The same authors advocated further control of baseline variability by controlling treatment conditions. Here, the conditions of treatment were not controlled to one operator since inter-operator variability is advantageous in representing a real life dialogue and would favour generalization of results to wider edentulous population. It is to be mentioned that despite the

above, clinical procedures were standardised since all operators were either qualified dentists or students conducting treatment under supervision of qualified dentists which allowed adherence to principles of complete denture fabrication.

Although the original study design did not exclude subjects willing to have implants to enhance denture retention of newly made CCDs (T1 and T3 without T2), none of the subjects had satisfactory baseline dentures and all underwent primary CCD treatment. This facilitated a complete data set throughout all stages for implant overdenture participants and facilitated better comparison between subgroups.

7.4 Examination of the PDI-CE diagnostic complexity of patients

Excellent inter-examiner reliability and reproducibility among investigators confirmed that PDI-CE classification is a useful tool for clinical assessment of edentulous patients' oral presentation (22). There is a common belief that the condition of the mouth will impact on denture success. Over two thirds (Figure 6-10) of subjects in this study fell into PDI-CE Class III and IV indicating substantially and severely compromised anatomical condition respectively. The distribution did not change when the classification was secondarily investigated among implant choice subgroups and denture satisfaction subgroups, Tables 6-9 and 6-10 respectively. To put it differently, very compromised clinical presentations were highly evident and similarly distributed for those who agreed or disagreed on implant treatment as well as for those who were satisfied or dissatisfied with new dentures. Even more interesting, there were slightly more patients with highly compromised presentations in the "Satisfied" group (67%) than in the "Dissatisfied" group (62%) - Table 6.10 (This difference was not tested for statistical significance). This suggests that neither implant

treatment decision nor denture satisfaction were driven exclusively by the objective clinical presentation of the patient. No previous studies comparing the relation between oral conditions and implant choice decision was undertaken, though extensive research (12, 22, 27, 59, 107, 140-144) was conducted to evaluate denture treatment outcomes and anatomical conditions of the mouth. Despite the dichotomy in the prosthetic literature about the association between oral anatomy and conventional restoration success, the majority of studies (22, 27, 59, 107, 140-143) that investigated the influence of clinical presentation on patient self-reported outcomes have found a weak or no correlation. Pan et al. (143), investigated 214 edentulous patients randomly allocated into two groups treated with CCDs or IODs and examined the relationship between mandibular bone height and self-reported satisfaction. He used four methods to classify the mandibular bone height including the PDI-CE classification used here and concluded that mandibular bone height had no effect on satisfaction. Van Waas in his two reports (59, 107), investigated this relationship using different statistical analysis on a cohort of 130 patients. It was found that the physical condition of the mouth and treatment satisfaction were not correlated. Overall these studies indicate that objective observations may not measure qualities of importance to the patient and, more importantly, what they measure may reflect technical aspects of treatment that the patient does not perceive at all (132). The results of our study concur with these findings since the PDI-CE classification fails to relate to treatment choices and patient satisfaction.

Contrary to the above, two studies found a positive correlation between oral condition and subjective variables. Close inspection of their study design question the relevance of their finding to ours. In the first, Magnusson (144) reported a positive relationship yet this did not reach a statistical significance; also, their findings were based on 39 participants only. The second study was by Fenlon and colleagues (127) in 2000 with a sample size of 723

participants. Using structural equation modelling analysis, they found a positive causal relationship between ridge anatomy and complete denture use. Ridge anatomy was considered a potential prognostic factor. This causal relationship was not related to patient satisfaction or OHRQoL but instead to the "use" of conventional dentures which may or may not be related to qualitative outcomes measures. However, the same research group in 2008 (145) have found that physical condition of the mandibular residual alveolar ridges was a strong determinant of patients' "satisfaction" with CCDs.

Clinicians and patients tend to evaluate treatment outcomes and success differently (22). Fiene et al. (132) found that the correlation between patients and dentists ratings of the same outcome measures or prosthesis was poor. This discrepancy was more marked when the presentation was worse in severity. When a dentist is encountered by advanced atrophy of residual alveolar ridges, the severity of the deficiency, supplemented by the complexity in treating such cases, may convince the dentist that the patient will have problems with their dentures. Clinicians desire objective diagnostic scales that provide a direct relationship to outcomes. However, objective scales do not seem be key measures in the management of edentulism for a few reasons. Firstly, as stated above the literature continues to question the importance of objective measures in treatment of edentulism. Secondly, the aims of edentulous patients' rehabilitation is to reduce the disability of the chronic condition, so patient-centred measures seem to be the logical and most valid outcome measures (132).

7.5 Investigation of the psychological trait of optimism of the participants using the Life Orientation Test

The Life Orientation Test (LOT) was used in this study for a few reasons. Firstly, most studies have used psychological scales that are long in nature (over 30 questions). Extending the length of the questionnaire booklet here would have increased the risk of participant fatigue, especially among this elderly cohort. Secondly, there are many aspects of personality that may be expected to relate to treatment of edentulism and/or OHRQoL, yet the literature has contradicting results about their significance (107, 114, 116, 127). On the other hand, optimism was found to be related to positive general health outcomes (146), positive life satisfaction (119) and a person's QoL (79). For example, Schou et al. (147) have examined the association between QoL and optimism (using a Life Orientation Test) in 165 women treated with breast cancer and found that optimism had a direct influence on QoL, where coping was a strong mediator factor. Similarly, optimism may be a good marker of personality that may influence perception of dental health outcomes, particularly in the management of edentulism. This assumption seems reasonable since the associations between optimism and health outcomes is mediated by coping strategies (146), an important link in adaptation to conventional denture treatment. No previous study has investigated optimism using the LOT among edentulous patients.

In order to see if the trait of optimism plays a role in treatment choice or response, the LOT scores were analysed in subgroups (Table 6-12). There were no statistically significant differences in LOT scores between those who chose to have implant treatment and those who were averse to this treatment option ($p = 0.19$). This suggests that the optimism trait was not an influencing factor on implant treatment decisions in edentulous patients. In the same vein,

mean LOT scores were similar for those who were satisfied and dissatisfied with CCDs after T2 (p = 0.43). Similarly, optimism did not appear to be a determining factor for the outcome of satisfaction in conventional denture treatment. These results could be attributed to our homogenous sample where the LOT scores among different edentulous groups were clustered in the middle range of the scale (Figure 6-11); most participants reported average optimism levels (Mean = 20, SD = 5.6) with only a few falling in the extreme ends of the scale.

A direct relationship between optimism and treatment outcomes in edentulism was not explored previously in the literature, making direct comparisons of our results impossible. Two publications (136, 148) examined the sense of coherence (SOC), a psychological factor highly correlated with optimism. SOC was not found to influence treatment outcomes. Although it is an indirect relationship, this supports our findings since no relation with the LOT was established for treatment preference or denture satisfaction.

7.6 Examination of "Dental Treatment Uptake Scale" scores in the edentulous subgroups

There is limited evidence on how edentulous people may consider or reject an implant treatment option. This dissertation tackles the subject from different angles. A research group from CUH in collaboration with DDUH (113) completed the first strand of this project whereby qualitative interviews of an edentulous cohort were used to generate more in depth information on treatment uptake. More flexible and responsive qualitative patient-based approaches were necessary to explore patients' perceptions of rehabilitation. Qualitative semi-structured interviews allowed for capture of information that may have been missed by limited-ended questionnaires or quantitative methods (149). Themes recognized from

interviews were employed subsequently to develop an inventory scale, the "Dental Treatment Uptake Scale" (DTUS) (113). Analysed DTUS data gathered from our participants, although preliminary, were quite promising in favour of the new scale. Those who were not satisfied with their conventional denture treatment after T2 reported significantly higher baseline DTUS scores ($p = 0.04$) than those who were satisfied with the same intervention (Table 6-14). This may suggests that people in the "Dissatisfied" group, whom conventional treatment was not satisfactory, were more demanding and were more apt to consider new treatment options if suggested by a dentist. Those who accepted an offer of implants after T2 had significantly higher baseline DTUS levels ($p = 0.01$) compared to those who rejected the implant option (Table 6-14). This may indicate, even before treatment, the presence of an intrinsic desire for treatment by some individual over others. The data suggested that DTUS might be a useful prognostic tool to highlight edentulous patients interested in implant treatment at baseline. Future studies to analyse DTUS validity and reliability are underway using a larger sample size as well as analysis of which questions contributed to these findings.

7.7 Comparison of groups based on implant choice, examining characteristics that may indicate treatment choice

Understanding patient characteristics that may lead to treatment choices is important in treatment success, since it was previously found that when an individual has no expectation of receiving implants, an IOD provides little advantage over properly constructed CCDs and the former was not perceived as a big improvement (110). Hence, IODs for certain people could be considered as overtreatment and a waste of funds. The opposite is also true where those likely to pursue implant treatment will show little benefit if treated with conventional

dentures. This is demonstrated in Table 6-19 where the "implant group" showed a small improvement in denture satisfaction scores after CCDs. The same group reported a remarkable improvement in denture satisfaction scores after IODs.

When comparing groups based on implant choice (Tables 6-15and 6-16), gender was not a differentiating factor since females predominated regardless of the implant treatment choice. Those who chose implants had statistically significant ($p < 0.05$) newer dentures at presentation (5 years) when compared to those who did not opt for implant treatment (14 years). RCT studies (135, 148) in which patients were randomized into treatment groups showed the expected no differences in socio-demographic factors among groups. On the other hand and in agreement to our findings, trials that considered patients' choices (54, 110) found that "Implant refusers" (n=12, mean age = 67.6 years) were also older than "Implant accepters" (n=33, mean age = 61.1 years). Our results were comparable where "No implant group" (n=102) aged 70.8 years on average and "Implant group" (n=21) aged 64.6 years on average (table 6-16). Seeking another conventional denture treatment while having a not very old denture might be a predictor that this patient will be more likely to opt for implant treatment. Furthermore, those who chose implants were statistically significantly ($p < 0.05$) younger in age than those who did not opt for implant overdentures. Means of "years of edentulism" and "number of previous dentures" did not differ among implant choice subgroups.

Similar to trends found here and in other studies (42, 93, 109, 110), both implant choice groups exhibited an improvement after conventional denture treatment in terms of OHIP and denture satisfaction (Tables 6-17 to 6-22). Comparable to findings in other studies (42, 109,

139), the overall improvement was also found to be greater for those who received IODs compared to those who received CCDs.

Randomized control trials by design would show no difference between the CCDs and IODs groups according to their DSQ and OHIP scores at baseline (135, 148). This is due to randomization which is a study prerequisite to test the treatment effect of an intervention. In our research where patients were assigned to different groups according to their own preferences, baseline OHRQoL and satisfaction scores for those who later chose implants were worse than those who did not want implants (Tables 6-17 to 6-22). This confirms the power of preference and that having the chance to choose is essential for patients and consequently reflects vital information for researchers and clinicians (132). In agreement with other studies (110), the different baseline outcome scores between groups reached statistical significance for OHIP total scores only ($p = 0.02$) and not for DSQ scores. This means, those who pursued implant treatment presented at baseline with greater impact on their lives caused by their prosthesis and/or the condition (high OHIP-EDENT total score) (Table 6.21). Not only that, the "Implant group" had worse OHIP scores than the "No implant group" at baseline; the former had even worse scores after CCD provision than the "No implant group" baseline scores. In other words, those who were likely to have IOD treatment in future had worse baseline OHIP levels than those who would not consider implant treatment after their primary treatment with CCDs. Another way to view the data was that there was more scope for improvement in the implant group but a considerable improvement occurred only after the provision of IODs. It is clear that the implant group had genuine problems at baseline captured by the OHIP instrument and these were alleviated only after implant treatment. Perhaps their poor OHRQoL made them want to try a new form of therapy which would give them the best chance of improvement. A review about how to use OHRQoL instruments by

Sischo and Border (79) pointed out the prognostic value of these tools and their use as predictor scales for treatment selection and/or treatment outcomes aside from the traditional use as survey research tools that identify if certain factors are at greater risk for low or high OHRQoL. The next step is to consider a larger sample that would allow further analysis of OHIP-EDENT and investigate which domains play a significant role in this prediction.

When another research trial considered treatment preferences, similar results and trends to here emerged from groups based on different preferences. Allen et al. (110) found that "Implant accepter" exhibited worse OHIP and satisfaction pre-treatment scores than "Implant refusers" and the difference was only statistically significant for the OHIP scores. They reported higher post-treatment total OHIP scores for the "Implant accepters" (n=33, mean=30.5) compared to our post-treatment total OHIP scores for "Implant group" (n=11, mean =14.18). Similarly, in their study they reported higher post-treatment total OHIP scores for the "Implant refusers" (n=33, mean=54) compared to our post-treatment total OHIP scores for "No implant group" (n=89, mean =25). This is mainly attributed to their use of the full version OHIP scale (49 statements) and the use of the abbreviated OHIP-EDENT in this study that contains 19 statements only. One explanation as to why OHIP measure was the only measure to exhibit a statistically significant difference is that OHRQoL is a multi-dimensional concept that incorporates a wide physical and psycho-social element in individual's life in relation to the condition and/or the intervention (78). On the other hand, satisfaction scales are just a reflection on how good or bad the preceding prosthesis was, which is only one part of the whole disability picture. Not all prospective studies found that OHIP baseline responses successfully predicted those who may be willing to consider an implant treatment option. Walton et al. (54) failed to establish this relationship. This might be

attributed to their use of OHIP-49 which contains questions not relevant to edentulous patients that compromise this tool's power when used in such a population (76).

To facilitate the use of OHRQoL scales among general dental professionals, it is important to simplify its relevance since non-researchers may not be familiar with those scales (135). Also, it would be useful to introduce cut-off points, or meaningful increments, to enable their use as an easy predictor tool. In an effort to quantify the amount of change that is compatible with a minimally important difference (MID), Jaeschke et al. (150) defined MID as *"the smallest difference in scores in the domain of interest that patients perceive as beneficial and that would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management".* John and colleagues (151) have developed an approach to explain the significance of changes in OHIP-49 instrument by comparing them to global ratings of change using a sample of 224 patients. Using this approach they suggested that a six point difference in OHIP-49 score could be regarded as the MID. A similar approach and calculation should be investigated in future to assign the equivalent MID for the abbreviated OHIP-EDENT as well as for the denture satisfaction questionnaire.

A secondary analysis was carried out to investigate the main obstacles preventing edentulous patients from taking up implant treatment. When patients were asked directly why they did not accept implant treatment, the most common and most reported reasons were satisfaction with new dentures and fear of surgery (Table 6-24). It was interesting to see that 5% said that they were too old for implants. The dental team should have an active educational role to explain that age alone is not a limiting factor for having implant surgery. Reasons for implant refusal in those who chose not to have implants and also agreed with the statement "if I could have implant treatment for free I would consider having it" (Table 6-26) in descending order

were: 49% satisfaction with dentures, 27% to avoid surgery, 9% cost of implants (although cost was minimal), and 7% osteoporosis. Asking patients in early assessment visits about potential fears of surgery, costs, and relevant medical problems would reveal more than 40% of barriers. Walton and colleagues (54) also found that about one third of those who rejected the offer of implants decided that surgical risks were not acceptable even when the cost was nothing. With elimination or substantially reducing the factor of cost it is apparent that fear of surgery is a critical obstacle. Similar to our results other investigators (54) also found that many participants were satisfied with their dentures and had no reason to request further treatment.

7.8 Investigation of groups based on satisfaction and baseline characteristics of edentulous patients that can indicate satisfaction and success for treatment

Gender was not a differentiating factor since females predominated regardless of the level of satisfaction (Table 6-27). Statistical mean comparison tests revealed that those who were dissatisfied with their new dentures at T2 were slightly younger in age than those who were satisfied (p = 0.05) (Table 6-28). Younger patients might have different needs than older, more accepting edentulous people. Dissatisfied participants had newer dentures at presentation (Mean = 9.96) in comparison to satisfied patients (Mean = 12.78) but this did not reach statistical significance. Means of years of edentulism and number of previous dentures were alike between satisfaction subgroups.

Generally, the majority of participants were satisfied with new conventional denture treatment (n = 84) compared with dissatisfied patients (n=28) (Figure 6-12). Similar findings

were observed in other studies (27, 54, 141, 144). It is reassuring to know that despite the shortcomings of conventional denture treatment many people can be satisfied, adapt well to their disability and manage to function using simple prostheses (6, 28-30, 54). Walton et al. (54) reported similar findings in this study conducted on Canadian participants and attributed this to the cultural and social surroundings of many complete denture wearers where discomfort and difficulties related with CCDs are accepted with resignation and without complaint, and where coping to dentures is promoted. This is comparable to findings of Meaney et al. (113) that found similar cultural reasoning reported by Irish adults wearing conventional dentures. On the other hand, those who struggle to cope are the ones who were extensively examined by many studies (including ours). Although a minority, they represent an important cohort of patients that have different needs and require public health strategies that identify them and possibly direct funds to provide them with complex implant based treatments.

Contrary to expectations, 84 participants were satisfied with their new CCDs at T2 yet some (n=12, 14%) chose to have implants when offered to them (Figure 6-12). This decision was a surprise but could have several explanations. This could be attributed to previous negative denture experiences, the fact that they were more open to consider new treatment options to improve their disability, or that they were attracted by the reduced cost and/or the minimal surgical invasiveness of implants. It would have been interesting to ask the satisfied patients why they opted to have implant treatment.

Even more surprising, 29 participants were dissatisfied with their new CCD treatment but a minority (n=8, 28%) chose to have implant treatment when offered (Figure 6-12). When asked why, half of the remaining 21 dissatisfied participants reported fear of surgery as their

main barrier (Table 6-29). We assumed that those who were dissatisfied with their dentures would be more inclined to choose implants particularly since small-diameter implants were used in this study. These implants are minimally invasive in nature and cause minimal operative discomfort and trauma. Reality clearly points out that treatment options involving surgery (no matter how cheap or minimally invasive) will cause considerable anxiety and will strongly influence a patient's decision. This is in agreement with previous findings where implant choice subgroups reported pain and/or fear of surgery as the major obstacles, even when the factor of cost is almost eliminated. Walton et al. (54) found that the most reported explanation for the refusal of implants was concern about surgical risks (43%). They advocated reasonably that the surgical consent form should equally include the potential benefits of implant treatment along with the potential complications. Other studies also mentioned fear of surgery (97, 109, 110) as being a major factor for drop-outs. This gives a rationale and explanation for the limited application of the treatment proposed in literature as the "gold standard" treatment for edentulous patients; that is, implant-retained overdentures (14, 15). It was cost that was largely thought to be the chief obstacle in the way of this conceptual therapeutic shift.

Patients' satisfaction and OHIP ratings of the original dentures at presentation were significantly worse in the dissatisfied group when compared to the satisfied group ($p < 0.05$) (Tables 6-33 to 6-38). For many patients, the most relevant treatment outcomes will be based on their last experience and how they were satisfied with the preceding intervention. This is particularly important since the outcome change after conventional denture intervention tends to be stable over time (93, 135, 141). Therefore, patients' outcome measures before treatment is an important prognosticator/predictor for treatment success (79).

7.9 Outcomes of small-diameter implants

It has been reported that dentures retained by narrow-diameter implants provide good patient satisfaction. Clinical success and survival rates for these implants appear to be acceptable (55, 59, 60). Although it is too early to report on the performance (survival, success, or complications) of the 24 small-diameter implants used in this study, no implant failure had occurred at the time this thesis was written. A soft tissue complication (peri-mucositis) occurred around one implant, but several prosthetic complications occurred in the form of wear of the Locator attachment's plastic inserts.

Few studies (55, 144, 152-154) have reported on outcomes with dentures retained by mini-implants in the mandible. Griffitts et al. (55), examined satisfaction of 30 patients who received four implants and Morneburg et al. (155) examined 67 patients who received two implants. Both research teams found a significant improvement in post-operative patient-based denture satisfaction, mainly in relation to functionality (comfort, retention, chewing ability and speaking). Scepanovic et al. (154) conducted a prospective study with 30 patients receiving 4 immediately loaded mini-implants in the mandible. They assessed QoL using the OHIP-EDENT questionnaire and denture satisfaction using questionnaires and Visual Analogue Scale (VAS). Outcomes evaluation was conducted twice: after wearing new CCDs, and again after wearing IODs corresponding to T2 and T3 in our study respectively. They reported a significant improvement in denture satisfaction aspects related to functionality ($p < 0.05$), total OHIP-EDENT (Mean = 23.46, $p < 0.001$) and all seven domains of the OHIP-EDENT scores ($p < 0.05$). Similar to these studies, the general denture satisfaction (DSQ Question 1), total DSQ, and total OHIP-EDENT scores in our study had all improved after implant treatment with mean differences between T2 and T3 of 1.3, 14.68, and 20.39 respectively. Those differences are based on the small number (n=12) of patients who

received and completed T3 interview and the statistical results of tests of such a small group will be inconclusive. This number should increase in future to at least 21 (those who considered implant treatment but not yet completed treatment). Statistical analysis shall be reconsidered then.

Reduced-diameter implants offer many potential advantages: they are minimally invasive, cause less postoperative discomfort, allow for immediate loading, and increased versatility of indications as they can be used in thin alveolar ridges that could not have been treated with implants otherwise, unless augmentation was considered (47-49). Despite those benefits, 82% (102 out of 125) rejected an offer of implants, with fear of surgery being a main obstacle. No matter how cheap it was or how much less discomfort it would cause, patients considered it as surgery and chose to avoid this treatment.

8 Limitations, future studies and suggestions

Patients in a dental hospital setting can be different than those treated in private practices, since patients may be referred to a dental hospital because of their clinical complexity or other patient-based factors. This may accounted for the higher percentage of complex oral presentations in our sample. On the other hand, withdrawal of routine funding of complete denture treatment from General Medical Scheme in the private sector has resulted in more referrals being made to the hospital service where treatment cost to the patient would still be covered. This means not only cases beyond the scope of the general dental practitioner are only being referred to be treated in the university-based set up. In addition, potential bias might have resulted from patients' ratings of OHRQoL that might be influenced by their cultural, psychological or interpersonal factors such as the clinical setting and relationship

with the clinicians (132). Many patients believe that a dental hospital setting provides the best possible treatment. Whether this sample can be assumed to represent the general population at large is unknown. Because of the hospital-based population, further research efforts with a diverse community sample would be interesting to compare with the results of this study.

The main limitation of this study was the small size of those who accepted implant treatment. Many reasons contributed to this: a high percentage of patients being satisfied with new conventional dentures made, strong treatment preferences, the long treatment journey for patients for fabrication of dentures by students, and long waiting lists for denture treatment and implant surgery. Therefore, results in relation to this group must be considered with caution. This is an ongoing project where more participants will be recruited and offered implant treatment in the future. Also, once all participants in the implant group complete their treatment, more T3 data will become available. Larger sample will allow for a mixed regression analysis to confirm our results using a multi-layered model. This is important since as a general rule multivariate data are better analysed using a multivariate method (127). This may reveal a more in-depth understanding since this dissertation is part of an ongoing project in DDUH and CUH with an overall goal of the development of a predictive model for treatment of edentulous patients. As mentioned previously, plans are underway for further analysis of DTUS data. Another strand involving the economic evaluation of the patients is also being studied by other investigators.

Long questionnaires may contribute to participants' fatigue. Attempts were made to reduce that by choosing shorter validated questionnaires and sometimes asking the patients to complete the questionnaire over two visits.

When implant treatment is provided at no financial cost, this may impact on patient perception of the positive value of this option in the "No Implant" group. For this reason implants were not provided free of charge but instead reduced fees were set against this treatment to render it affordable, yet eliminating the likelihood of patients asking for unnecessary treatment. The presence of 9% of implant refusers who reported that cost was their main obstacle supports the study design. On the other hand, some patients who were satisfied with their conventional complete dentures accepted implant treatment. Satisfaction is subjective, even in other aspects of life it is not uncommon for people to pursue better options despite being reasonably content with their current status. It is not uncommon to have patients who seek more treatment just to provide an improvement to an already well-functioning prosthesis.

There is little evidence and there is a need for studies that:

- Address questions directly related to individuals' true values and priorities
- Study psychological influences of optimism in management of edentulism
- Investigate characteristics of edentulous people who are likely to consider or refute an implant treatment option
- Assess of the predictive value of OHRQoL in treatment choices among a larger sample
- Simplify meaning of OHRQoL scales to the general dental professionals in terms of introducing cut-off points or meaningful incremental measures to enable its use as an easy predictor tool

Chapter Five

Conclusions

9 Conclusion

Within the limitation of this study, the results of the current study suggest that:

- The provision of conventional dentures or implant-retained denture improves patient-reported satisfaction and quality of life. For people who chose implant treatment, mandibular two-implant overdentures provide significantly better satisfaction and oral health related quality of life over conventional dentures.
- Although PDI-CE is a reliable tool to classify the clinical condition of the mouth, clinical presentation does not reflect a patient's level of satisfaction with conventional dentures. Objective tools are a poor predictor for an edentulous patient's future choice regarding implant treatment
- Optimism is not a determining factor for the outcome of satisfaction with conventional denture treatment or for implant treatment decisions in edentulous patients
- A Dental Treatment Uptake Scale can be a useful tool to predict edentulous patients interested in implant treatment. Participants dissatisfied with conventional dentures have a greater acceptance of complex dental treatment compared to satisfied patients
- The majority of patients after conventional denture treatment were satisfied with treatment and did not choose implants.
- Characteristics significantly related of those who are likely to choose implant treatment in future include: having newer denture at presentation, being younger in age, and reporting low baseline OHIP.
- Fear of surgery is a major barrier to accepting implant treatment in dissatisfied edentulous patients with conventional treatment. Implant refusal was high even when

implant cost is reduced substantially and/or the surgical invasiveness is minimized (small-diameter implants).

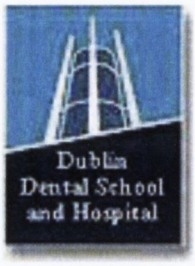
- Patients outcome measures (patients satisfaction and OHIP ratings) before treatment are important prognosticators for future treatment success

Chapter Six

Appendices and References

10 Appendices

- **Appendix I: Participant information leaflet**







Study Information Leaflet

The Predictive Value of Patient-Based Questionnaires in Treatment of Edentulism

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 will try to find out which people will have success with dentures and which may need more extensive treatment, such as implants. To do this, we plan to examine and interview a range of people who have different experiences with dentures.

How will the study be carried out?

The study involves an interview with a dentist where you will fill out three questionnaires and have an examination of your mouth. This should take no longer than 30-45 minutes. If

you have dentures made at the Dublin Dental University Hospital and University College Cork, you will be asked to fill in the questionnaires for the second time. This should take less than 30 minutes.

The examination will take place at the Dublin Dental Hospital and no dental treatment will be involved. A qualified dentist will look in your mouth with a mirror and ask you questions about how the loss of teeth is affecting your life.

How do I take part?

In order to participate, you must have had all your natural teeth extracted at least 3 months ago and have had a set of complete dentures made (whether you wear them or not doesn't matter). You must be referred to the Dental Hospital for new dentures.

Benefits

Taking part in the study should give you a better understanding of your clinical condition. In future we hope to use this information to identify patients who need implant treatment so we can design a service for them.

Are there any risks?

No risks are associated with this study as it involves a simple examination to look at your mouth and 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 dentures
- You are under 18 years of age
- You cannot understand or complete questionnaires
- You are severely ill
- You have a terminal illness
- You have a mental illness or 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.

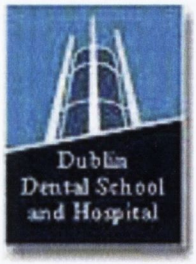
Permission:

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

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 Sittana Ahmed (Principal Researcher) who can be telephoned at (01) 612 7312. 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.

- **Appendix II: Informed consent**







INFORMED CONSENT FORM

PROJECT TITLE:

The Predictive Value of Patient-Based Questionnaires in Treatment of Edentulism

PRINCIPAL INVESTIGATOR
Dr Sittana Ahmed

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 will try to find out which people will have success with dentures and which may need more extensive treatment, such as implants. To do this, we plan to examine and interview a range of people who have different experiences with dentures.

DECLARATION:

- I agree to attend the Dublin Dental Hospital/ University College Cork to complete questionnaires about the impact of tooth loss and to have an examination of my mouth.
- 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: _____

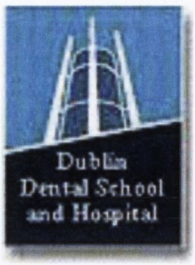
Date:_____

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: _____

- **Appendix III: Letter to prospective participants**







Department of Restorative Dentistry and Periodontology,

Dublin Dental School and Hospital/ Cork University Hospital

Dear _____

I am writing to ask if you would agree to participate in a research project at the Dublin Dental Hospital/University College Cork. We are investigating the success of denture treatment among a wide group of patients with no remaining natural teeth. We hope to learn how to predict which people will wear dentures successfully and which may need implants. I am contacting you because you were recently referred to the Dental Hospital for dentures and may be suitable for our study. Participation in the study is completely voluntary.

This study includes people who have had all their teeth extracted at least three months previously. Your participation involves filling in some questionnaires and a brief clinical examination. You will be asked to repeat the questionnaires if you have dentures made at the Dental Hospital.

Either myself or another dentist on the research team will perform the examination to look at your mouth, using a small dental mirror. Completion of the examination and questionnaires will take place in the Dental Hospital. This should take about 45 minutes.

We hope that by taking part in this study you will achieve a greater understanding of your oral condition. Results of the project may help future patients to access suitable care more quickly.

Please read over the enclosed information leaflet and consent form. You can get more information on any aspect of the study, your participation in the study, and your rights from me at (01) 612 7312. If you are interested in joining the study, please fill out your details (below) and return the form in the enclosed stamped addressed envelope. We will then contact you to arrange an appointment.

Yours faithfully,

_____

Dr Sittana Ahmed

(Principal Investigator)

I agree to be contacted about joining the denture research study

Name:_____

Date of Birth:_____

Mobile Phone Number:_____

Home Phone Number:_____

E-mail:_____

PLEASE RETURN THIS PAGE IN THE ENVELOPE PROVIDED

- **Appendix IV: Information for implant placement**

The Predictive Value of Patient-Based Questionnaire in the Treatment of Edentulism

Information for implant placement

Thank you for your participation in the research project on satisfaction with denture treatment. We greatly appreciate your time and co-operation. Now you have new dentures, we would like to explain the options from here:

1 No further treatment

2 Placement of 2 small-diameter implants to stabilise your lower denture

This is a fairly new development in implant dentistry. It involves the placement of 2 small implants (2.9 mm diameter) in your lower jaw, which requires a minor surgery with local anaesthetic. After a healing period, your lower denture will be fitted with attachments that fit the top of the implants and help to keep it in place. It is expected that the placement of small implants will be fairly simple, but there is less long term evidence than with larger implants. COST : €150*

3 Placement of 2 regular implants to stabilise your lower denture

This is a well-documented treatment in implant dentistry. It involves the placement of 2 implants (3.25-3.75 mm diameter) in your lower jaw, which requires a minor surgery with local anaesthetic. After a healing period, your lower denture will be fitted with attachments that fit the top of the implants and help to keep it in place. These implants have a good track record, but may be difficult to place where the jawbone is very thin. COST : €1900*

*IMPORTANT NOTE: All implants and dentures require regular check ups and maintenance. For example, the implant attachments become worn and will need to be replaced. Likewise, dentures lose their fit or appearance over time. There will be additional cost for the future maintenance of your dentures and implants.

WITHDRAWAL

If you decide NOT to have implant treatment, please tell us the main reason why (TICK ONE)

Cost of implants ☐

Time it takes for implant treatment ☐

To avoid a surgical procedure ☐

Satisfied with my dentures ☐

Other reason (please specify) ☐

_____

- **Appendix V: Consent for implant placement**

The Predictive Value of Patient-Based Questionnaire in the Treatment of Edentulism

Consent for implant placement

Hospital Number:
Patient Name:
Date:

If you have any questions, please ask the attending surgeon BEFORE signing.

I hereby consent to the placement of 2 titanium implant fixtures into existing bone of the jaw, which will be used to stabilise the lower denture.

I have been informed of the alternative forms of treatment including no further treatment or the placement of more implants for a fixed denture.

The surgeon has explained to me that there are certain potential risks in this treatment procedure which include:
Common:

- Bleeding/bruising.
- Pain/discomfort
- Swelling

Uncommon:

- Injury to a nerve resulting in numbness or tingling of the chin, lip, cheek, gums and/or tongue on the operated side which may persist for several weeks, months or occasionally the effects may be permanent. (Lip/chin 1%, Tongue 0.1%)
- Postoperative infection
- Mechanical failure of the implant (immediate)
- Failure of the implant to integrate (delayed)
- Stretching of the corners of the mouth with resultant cracking and bruising
- Other_____

I consent to the use of xenografts (bovine materials), alloplast (synthetic) materials and allografts (processed bone) if necessary ☐
I consent to my records including radiographs, models or photographs being used for educational, audit or research purposes ☐
I consent to any teeth/tissues that need to be removed as part of the treatment plan, being retained and used anonymously for educational, audit or research purposes ☐
I accept the costs associated with this surgery and this has been discussed with me ☐

Patient's Signature Date

Surgeon's Signature Date

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