EVALUATION OF PATIENT-CENTERED OUTCOMES WITH CONVENTIONAL, OVERDENTURE, AND PALATELESS OVERDENTURE USING GUIDED MAXILLARY IMPLANT PLACEMENT

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ABSTRACT

Kimberly K. Schlam: Evaluation of patient-centered outcomes comparing conventional, overdenture and palateless overdenture using guided maxillary implant placement (Under the direction of Ingeborg De Kok)

Improved quality of life following insertion of mandibular dental implants for dentures and removable partial dentures is well established. Whether similar favorable outcomes occur in the edentulous maxilla following rehabilitation is unknown. In this study of 15 patients, a fully guided approach to implant placement with new dentures ensured accurate transfer of implant position and correct angulation. To assess the impact of rehabilitation stages on quality of life, the 49-item Oral Health Impact Profile (OHIP-49) was administered at baseline and again at 10 weeks following three treatment stages: post-insertion of conventional denture; post-pickup of locators in complete denture; and post-insertion of palateless overdenture. Change in mean severity score was tested for statistical significance using linear mixed models. Scores decreased significantly, signifying a reduction in the adverse impact of patient's dental problems on oral health quality of life. These observations support treatment of the edentulous maxilla with a 4-implant retained overdenture.

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"It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly…" —Theodore Roosevelt

"Imperfections are not inadequacies; they are reminders that we're all in this together."
— Brené Brown

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologists
CBCT	Cone Beam Computed Tomography
CD	Complete denture
COPD	Chronic Obstructive Pulmonary Disease
DAP	Dose Area Product
DICOM	Digital Imaging and Communications in Medicine
DMFT	Decay, Missing, Filled Teeth
FOV	Field-Of-View
GOHAI	Geriatric Oral Health Assessment Index
HbA1C	Hemoglobin A1c
HIPPA	Health Insurance Portability and Accountability Act
IOD	Implant Retained Overdenture
ISFDP	Implant Supported Fixed Dental Prosthesis
kVp	Peak kilovoltage
mAs	Milliampere second
mGy/cm2	Milligray per centimeter squared
OD	Overdenture
OHIP	Oral Health Impact Profile
OHIP-20E	20 Item Shortened OHIP for Edentulous Patients
OHIP-49	49 Item OHIPOHRQOL Oral Health-Related Quality of Life
oPRDP	over Partial removable dental prosthesis
OVD	Occlusal Vertical Dimension

P-11	panoramic x-ray
PE	Partially edentulous
PRDP	Partial removable dental prosthesis
SD	Standard deviation
QOL	Quality of Life
UNC	University of North Carolina
VAS	Visual Analog Scale
WHO	World Health Organization
μm	micrometer

INTRODUCTION

1. Epidemiology

National epidemiologic surveys show decreasing prevalence of edentulism in the United States population.[1] Given this decline, one would reason that the fabrication of prostheses for the edentulous patient would continue to decrease. Douglass et al. argues that attention must be paid to the demographics of this population in which the "denture market" can be estimated. Although not all edentulous individuals seek prostheses, he estimates that "the 10% decline in edentulism which has been experienced each decade for the past 30 years will be more than offset by the 79% increase in the adult population older than 55 years." It is therefore anticipated that the need for edentulous treatments will continue to increase through the year 2020 and that training for the fabrication of complete dentures in dental schools should not be abandoned.[2,3]

Felton states that given the many co-morbid conditions of edentulous patients, additional socioeconomic factors play a substantial role which include culture, dental aptitude, and access to care.[3,4] Disparities in the edentulous population exist for race and sex, and edentulism has been found to be inversely related to both education and income levels. When further evaluation was conducted for disparities in race, it was shown that when controlling for education level and income, this disparity was no longer significant. These authors suggest that much of the racial/ethnic disparities found in the

United States can be explained by socioeconomic factors. Edentulism was found to be 6 times higher in low-income families as compared to high income families as reported in Canada in 2003.[5] Although public assisted programs in the United States, such as Medicaid, aim to reach these populations, they have decreased rather than expanded dental coverage in recent years. These services cover limited dental services for those who often require them the most.[4]

A meta-analysis conducted by Kassebaum et al. indicated that complete edentulism has declined globally from 4.4% to 4.1% from 1990 to 2010.[6] However, comparisons of the prevalence of complete edentulism between countries has proven difficult as the rates vary significantly even between regions within each country. Emami et al. describes that the differences between provinces range as much as 14% as seen in Quebec to only 5% seen in Northwest Territories, which he relates to access to fluoridated water and smoking. Studies reviewed found that the prevalence of edentulism in the elderly from different countries ranged from 6% to over 50%.[5]

Edentulism is considered, much like medical conditions such as hypertension, to correlate with an aging population. Importantly though, variability in tooth loss reported throughout the world suggests that it is not an inevitable outcome. Marcus et al. states "These declines (*in rates of edentulism)* highlight several important aspects of tooth retention: (1) losing all of one's natural teeth is not an inevitable part of human aging; (2) the proportion of persons with at least some of their natural teeth has been growing; and (3) the retention of natural teeth for an entire lifetime is increasingly possible for each successive cohort of adults in the US." As advances in dentistry has made tooth extraction a less than ideal treatment option, younger cohorts are inevitably exposed to

less extraction based philosophies and are likely being offered additional treatment options at more comparable prices.[1,7] Similar to reports of adaptation to various medical interventions, it has been reported that adaptation to new dentures due to oral motor abilities is not clearly age related as aging is a biologic process rather than a chronologic process.[8,9] This coincides with the vast individuality seen in the adaptive capacity of any dental prosthesis.

Today's technology has enhanced distribution of the knowledge of individualized health care and we can use this increased awareness to better appreciate how daily choices such as food and physical fitness can result in dramatic changes in the aging process. As the number of people who use this accessible information to make more beneficial health decisions grows, we see a more robust older population seeking dental treatment. Unfortunately, like other disparities seen in medicine, the inability to afford to make these choices continues to perpetuate a lack of general health across all ages. Great attention should be given to the individuality of the patient considering treatment options rather than their chronologic age. Their dexterity, maintenance required for the future of the treatments, as well as etiology of past dental complications, can be important predictors for the prognosis of the next dental prosthesis. Given falling rates of edentulism at a young age combined with an increasing life expectancy, many people are losing teeth later in life at a time when it can be particularly difficult to both adapt to a new prosthesis and maintain a proper level of oral hygiene.[10] As expressed eloquently, "Edentulism remains an individual concern, a professional responsibility, and a prominent public health issue."[11]

2. Treating the Edentulous patient

2.1 Comprehensive Care

Due to their inability to eat and speak effectively, two of the essential tasks of life, edentulous patients are considered disabled. According to the World Health Organization (WHO) criteria, the completely edentulous patient meets criteria for being: (1) physically impaired, (2) disabled, and (3) handicapped.[12,13] It has been well documented that the orofacial region is crucial to a patient's functioning and has been described by Giddon et al. as critical to survival in (1) the need to eat and drink, (2) the detection of precancerous and eroding lesions which often accompany prosthetic application and change in oral environment, (3) social well-being for communication and self-esteem, and (4) the quality of life resulting from enjoyment of food, talking, music, and expressions of love.[14]

Emami et al. describes in a 2013 review article the impact of edentulism on both oral health and general health in a concise outline which will be used to describe the comprehensive edentulous patient. The impact on oral health is described in the following categories: tooth loss as a modifier for normal physiology, tooth loss as a risk factor for impaired mastication, and tooth loss as a determinant of oral health. In discussing the effects on general health, the following categories were created: the impact of dentition on nutrition as it relates to comorbid conditions and weight gain, as well as disability and mortality. Finally, the impact edentulism plays on patients' quality of life is addressed.[5]

2.2 Tooth loss: Impact on normal physiology, oral health and mastication

Alveolar bone exists solely to support teeth and as teeth are lost, bone is lost dramatically within the first 6 months and then lost continually at a lesser rate throughout the life of the patient. Although it has been shown that the mandible loses bone at a rate four times that of the maxilla, overtime the bone loss in both arches has shown to negatively affect denture bearing areas such that intra and extra oral architecture is affected. Fabrication processes of conventional dentures have attempted to identify regions of most stable tissue for support, however prosthetic rehabilitation becomes increasingly challenging with each loss of tissue for support and retention. Loss of facial soft tissue support as well as loss of occlusal vertical dimension results in an unesthetic, “aging” appearance which relies on prostheses for improvement. These anatomic changes over time appear to be unique to each individual and it is suggested that the related factors are age, gender, duration of edentulism, parafunctional habits, general health, and various disease processes.

While placement of dental implants has shown significant improvement for patients with poor remaining residual ridge architecture, positive responses to preventing bone resorption in the areas of implant placement has also become widely recognized. It is suggested that a combination of the use of dental implants with proper prosthetic maintenance is crucial for prevention and management of residual ridge resorption.[11]

It has been found that denture related mucosal lesions account for 8.4% of all oral mucosal lesions and that they: occur frequently, may be associated with pain, and may be related to other co-morbid conditions.[15] In 2009, Cooper reviewed the biologic

impacts of the current and future treatments for the edentulous patient and suggested that it is denture use, not edentulism, that is associated with the prevalence of oral mucosal lesions. Individual cleanliness, nocturnal or continual use of dentures, as well as individualized biofilm plays a role in how these lesions form and progress. He suggests that we have limited information on the biofilm of the edentulous adult wearing complete dentures and that attention should be paid to this since oral bacteria have been implicated in various medical complications such as bacterial endocarditis, pneumonia, chronic obstructive pulmonary disease and gastrointestinal infection.[11,16] He further suggests that the relationship of oral inflammation of these patients with chronic systemic diseases should continue to be evaluated.

According to a systematic review, individuals with less than 20 teeth, or 10 contacting units of teeth, have impaired masticatory ability and efficiency.[17] A study by Slade et al. investigated dentate and edentulous patients' chewing capacity. They found that 58.6% of edentulous patients reported difficulty in chewing various food groups, compared to 6.1% of patients with fewer than nine missing teeth.[18] Further comparing masticatory force between dentate and denture wearers, studies agree that denture wearers have significantly less bite strength and require about 7 times more chewing strokes to masticate the same piece of food.[19] It has also been shown that these patient's masseter muscle thickness is less than that of dentate individuals, and that this may correlate with their ability to chew hard foods.[20]

Denture wearers commonly report frustration while eating due to their loss of adaptability and compensatory ability. Giddon states that patients with natural dentition have the ability to compensate for less time or fewer masticatory strokes with foods by

increasing the force of each chewing stroke, however, the denture wearer cannot do so because of reduced chewing efficiency. Studies have shown that edentulous patients restored with maxillary and mandibular conventional complete dentures have only 30% of the masticatory efficiency as compared to fully dentate individuals.[21] As eating has been described as a complex experience of sensory and motor function, these patients often loose interest in difficult to eat foods and narrow their diet to those which are easily attainable.[14] Adaptation to edentulism, and a prosthesis, is an individual experience. It has been shown that some patients with well fitting, painless prostheses, restrict their food choices while others with poorly fitting prostheses consume anything available.[22] Although responses to edentulism have been varied, research has clearly demonstrated that tooth loss negatively influences food selection.[23]

2.3 Tooth Loss: Impact on General Health

Felton has summarized the vast array of co-morbid conditions related to the edentulous patient. He states that one of the most difficult things related to these complicated co-morbid conditions is determining if they are causal or casual. The relationship between tooth loss and other systemic comorbid conditions is, at best, multifactorial. This complex situation is depicted schematically in Figure 1 by Felton; the complex oral-systemic disease paradigm.[3]

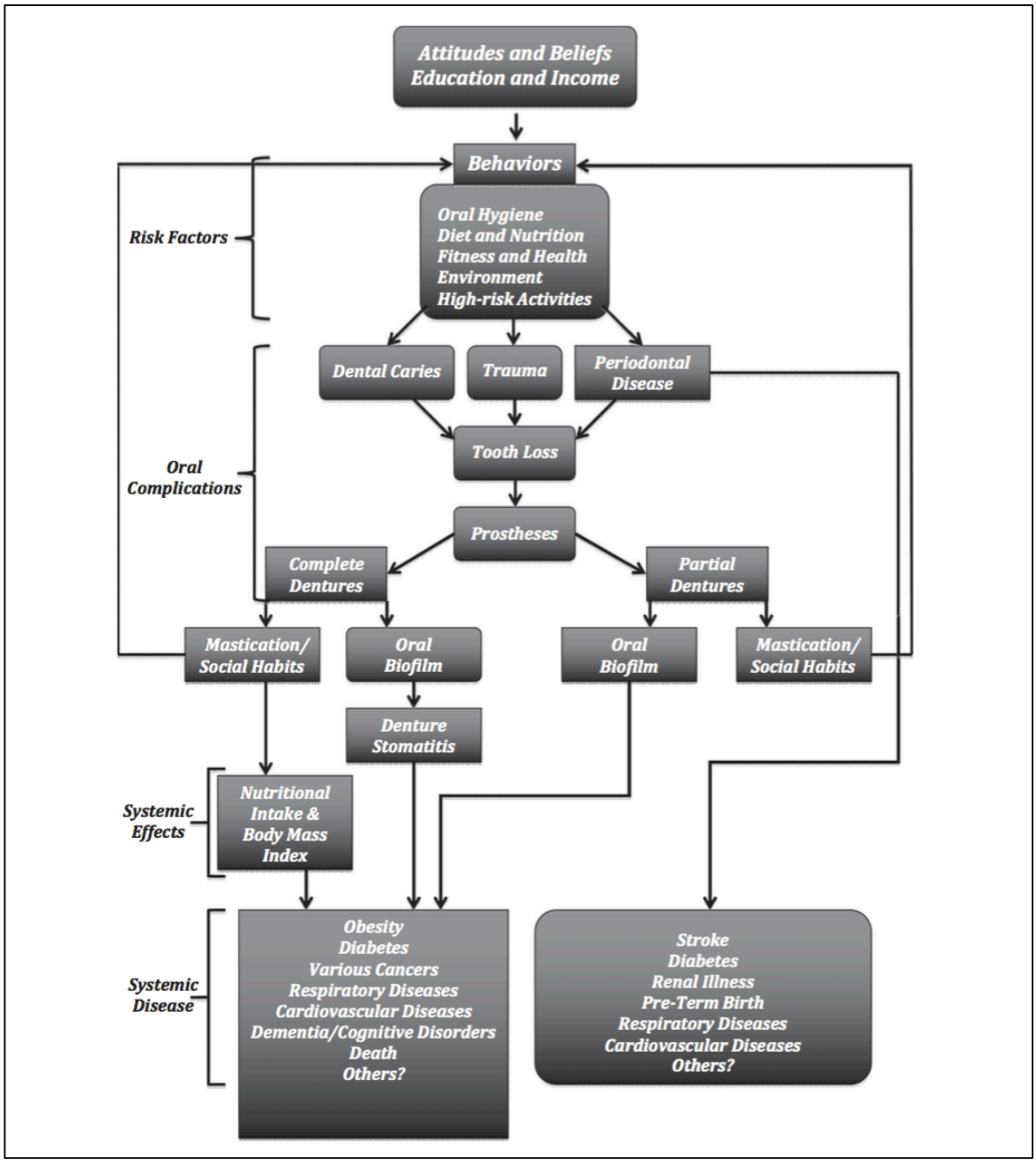


Figure 1: The complex oral-systemic disease paradigm

Felton evaluated edentulism and its relationship to the known co-morbid conditions of: impact on nutrition and obesity, cardiovascular diseases, diabetes, rheumatoid arthritis, respiratory diseases, cancer, cognitive disorders, and mortality.

Studies he reviewed concluded that tooth loss negatively affects patients' food choices, altering their intake of vital nutrients and eventually leading to malnutrition. It was found that the edentulous patient is 3.26 times more likely to suffer from malnutrition than their partially dentate comparison, however, the use of a complete prosthetic did show improvement in the status of malnutrition.[24,25] Lack of proper mastication often forces patients to eat bigger pieces of food which puts additional stress on their gastrointestinal system in attempt to break down food. Further complications arise as these patients avoid difficult to chew fibrous foods, causing constipation and perpetuating further discomfort and systemic challenges. A 3.28 times greater risk for obesity was also found in the population who had less than 8 remaining teeth.[24]

Secondary to identifying the myriad of comorbid conditions, Felton concluded that the edentulous patient is at risk for reduced nutritional intake and obesity, an increased risk of chronic obstructive pulmonary disease (COPD) related events, a decline in cognitive function, and may be associated with an increased risk of head and neck cancer. He further determined that poorly maintained removable prostheses may be associated with increases in pneumonia-related hospitalizations. Edentulism was found to be an independent predictor of cardiovascular disease mortality and a reduced, but not replaced dentition, is associated with an increased risk for mortality. He further concluded that education for these patients and their caregivers is crucial, as wearing optimally maintained removable prostheses may help protect against the aforementioned co-morbidities.[3]

Similar findings of the systemic effects of tooth loss were summarized by Emami et al. into the following: (a) a lower intake of fruits and vegetables, fiber, and carotene

and increased cholesterol and saturated fats, in addition to a higher prevalence of obesity, can increase the risk of cardiovascular diseases and gastrointestinal disorders; (b) increased rates of chronic inflammatory changes of the gastric mucosa, upper gastrointestinal and pancreatic cancer, and higher rates of peptic or duodenal ulcers;(c) increased risk of noninsulin-dependent diabetes mellitus;(d) increased risk of electrocardiographic abnormalities, hypertension, heart failure, ischemic heart disease, stroke, and aortic valve sclerosis; (e) decreased daily function, physical activity, and physical domains of health-related quality of life;(f) increased risk of chronic kidney disease;(g) association between edentulism and sleep-disordered breathing, including obstructive sleep apnea.[5]

Poor diet causing malnutrition has shown clear correlation to poor general health. Difficulty masticating foods as well as decreased enjoyment of them can be related to patient food choices but it is also important to give attention to the psychological and social aspects of eating. Self-identification as disabled may cause patients to have less self-esteem and therefore pay less attention to keeping themselves healthy. Social interaction has been termed a reflection of self-esteem, and those who do not identify with and integrate their prosthesis as a part of them may never adapt.[14] If eating certain foods proves difficult, avoidance of embarrassment may keep patients from eating in social situations. Furthermore, if patients believe that their prosthesis is unaesthetic or unnatural looking, they may avoid social situations altogether.[26] It is known that social seclusion may lead to depression and further lack of self-worth which perpetuates unhealthy behaviors both physically and psychologically.[27] Depression has been

identified as a co-morbid condition for the edentulous patient which affects the acceptance and prognosis of continuing treatments.[11]

It is important to consider the effects our prostheses have on our patients but it is also important to consider how the systemic health of our patients affect the prognosis of our prostheses. Xerostomia is a common complication plaguing our edentulous patients often as a side effect of over 400 medications.[27] Given the extent of comorbid conditions described by Felton, it is common that edentulous patients are taken more than one saliva altering medication. Xerostomia has been shown to affect taste resulting in many foods that appear to have a metallic and salty taste often causing the patient to have unhealthy cravings for sugar. Inadequate quality and quantity of mucous saliva is particularly challenging for treatment with complete dentures as it is necessary to aid in retention and seal and lubricate the dentures during talking and eating. Attempts can be made to manage these patients' hypo-salivation either through systemic sialogogues or artificial saliva substitutes, however it continues to pose a lifelong challenge for these patients.

2.4 Tooth Loss: Impact on Quality of Life

Quality of life (QOL) is defined as an individual's perception of his or her position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, and concerns.[5] Perceptions of how oral conditions affect daily function and well-being are referred to as Oral Health-Related Quality of Life (OHRQOL).[5]

As it has been stated earlier, edentulous patients can be considered physically impaired, disabled, and handicapped, therefore we would expect them to rate their

quality of life lower than a comparable dentate patient. The functional and esthetic sequelae of the edentulous state are unique to each individual and as such the perceptions of the edentulous state range from feelings of inconvenience to feelings of severe handicap.[27] Edentulism affects many domains of quality of life as it not only affects physical experiences of the patient such as mastication and esthetics, but also psychological experiences of social interaction and self-esteem.[11]

It is well known that clinicians and patients do not judge or experience treatments in the same manner; a clinician may appreciate additional technical expertise which may be neglected by the patient and conversely the patient may appreciate something that the clinician is ignorant to. This is apparent in denture fabrication as studies show patients do not show preferences for dentures fabricated through lengthy technical conventional methods compared to those processes which combine steps.[28] Similarly those treatments which we believe may bring patients greater satisfaction, such as a fixed prosthesis compared to a removable one, have shown no statistical preference of one over the other.[29] Because of this, exclusively using clinical measures to evaluate treatment has been determined inadequate and it is recommended that a focus be put on patient reported outcomes. Times have changed significantly from the idea of the dentist as an authoritative figure and now the clinician is seen as teacher present to help the patient make the best decision for their unique healthcare needs.

Although it is easy for clinicians to focus on technical aspects of our prostheses, it is clear that particularly for the edentulous patient it is important to pay attention to the broad array of concerns during treatment as well as in the maintenance phase. Giddon

et al. suggests that the total orofacial impact must be considered as it is essential to the quality of life particularly for the geriatric patient.[14]

3. Treatment Options

Feine at al. describes people who have lost all of their teeth as those who will suffer the chronic condition of edentulism as well as the effects of their chosen treatments on their well-being. Traditional treatment modalities for the rehabilitation of edentulous patients focus on replacement of lost physical parts in the hopes to also improve function and esthetics. Subsequently, removable dental treatments were initially evaluated based on patients' residual anatomy often dictating the level of technical skill required and difficulty of fabrication. These evaluations included bite force, functional tests of mastication, as well as patient esthetics. Research has shown that clinician determined clinical successes or failures and patient reported assessments of their treatment do not equate.[30] Therefore, it is recommended that more patient reported information is required to evaluate successes and failures of these prostheses.

When considering implants to facilitate dental rehabilitation, factors related to an individual's biologic age should be considered. Although current studies show similar success and survival rates for dental implants placed at all ages, other risk factors related to aging include the onset of dependency for daily living as well as their plethora of co-morbid conditions. As maintaining daily activities as well as general health has proven difficult for many elderly, the maintenance of implant prosthetics is often not of primary concern.[10] Müller also highlights that little is known about the prevalence and pathophysiology of peri-implantitis in geriatric patients, and that we may face significant

challenges related to this in the future. He continues by suggesting that “for geriatric patients, it seems imperative to add ‘management of implant prosthesis and ability to maintain oral hygiene’ to the success criteria mentioned previously.”[10] As all patients require unique treatment planning, Müller suggests that although many treatments may be prescribed for a given medical condition, the theoretically ‘ideal’ plan is one that must also be modified to a more rational treatment plan that takes into account the patient’s functional state and autonomy as well as the cost–benefit ratio.

Regarding cost as a consideration of treatment options for the edentulous patient, comparing the addition of implants for dentures, it has been shown that implant overdentures cost between two and three times that of complete dentures. The review by Carlsson et al. suggests that variations in costs are influenced by materials used, clinical setting, country, dental healthcare system and type of insurance and that for many patients this higher initial fee is a prohibitive factor.[30]

Given the factors affecting patients’ treatment decisions, Carlsson et al. suggests that the standard of care cannot simply be a certain type of prosthesis, rather it has to fulfill the following criteria: “pain- and infection-free oral comfort, oral condition that allows masticating unblended meals, restoration of lower face height and physiognomy, age-adequate and pleasing dental appearance, providing sufficient retention for self-confident interaction in a social context, use of biocompatible and inert materials, ‘natural’ speech. If the patient’s condition no longer allows the foregoing criteria to be met, the standard of care can be worded more generally as follows: primum non nocere (first, do no harm), restore aesthetics, oral function and

comfort, assure good oral health-related quality of life (OHRQOL), provide subjective patient satisfaction and well-being."[30]

It is important that all patients maintain relationships with their restoring dentist for regularly prophylaxis, continued evaluation of hygiene, as well as maintenance of various components used in complex rehabilitations. Müller states that care should be taken to ensure that implant patients in particular do not 'disappear' from the dentist's recall, particularly if they are older and become institutionalized. He suggests that by closely monitoring these patients, strategy can be used to create prostheses that are 'reversible' such that if attachments and hygiene become too complex for the aging patient, can be removed and converted back to a conventional prosthesis.[10]
Cooper states that attention must be paid to the uniqueness of the etiologies of tooth loss as it shows great insight into the prognosis and survival of a new prosthesis. He describes the etiology of tooth loss as largely from microbial disease affected strongly by behavioral influences, with the remainder of the edentulism being linked to iatrogenic, traumatic, and therapeutic causes.[11] As history has shown to often repeat itself from a biologic and behavioral perspective, this should be a strong factor in considering treatment choices.

The following treatment options for the edentulous maxilla will be considered in the realm of pros and cons as found in the literature: a) conventional denture, b) implant retained overdenture, c) implant supported fixed dental prosthesis, d) conus prosthesis; implant supported removable dental prosthesis.

3.1 Conventional Denture

Zarb suggests that over time, the technical skills and scientific rationale for fabrication of conventional dentures have continued to improve and have shown to contribute to an improved quality of life for the edentulous patient. He highlights that the conventional denture in particular remains an integral part of dental treatment and that particularly in the public health context it remains a relatively simple and inexpensive treatment method. Given challenging anatomic and medical conditions, conventional denture success greatly varied among individuals, it offers a universal application although “not a panacea for the edentulous patient.”[27]

It is known that maxillary conventional dentures are more widely accepted by patients compared to those in the mandible and studies comparing outcomes revealed that stability and comfort are among the features that distinguish maxillary denture acceptance from more generalized mandibular denture dissatisfaction.[31] Most studies have failed to show patient preference for technique of denture fabrication, tooth arrangement, occlusal scheme or type of articulator used.[31]

In his review, Müller decribes the mechanisms of conventional dentures and the challenges this presents for the aging patient. He states that mucosa-borne dentures function based on the interplay of three mechanisms; “First, they are retained by physical suction, as obtained by selective tissue compression during impression making or the creation of a posterior palatal seal. This mechanism requires a thin film of saliva, preferably of mucous consistency. However, over the time a denture is worn, physical retention decreases, as the denture-bearing bony structures atrophy along with ageing and occlusal load bearing. As physical retention decreases, the importance of

‘muscular’ retention increases, relying on learned skills to keep the denture in place during function. To successfully perform such a skillful task, the brain processes afferent information from the oral cavity which is then translated to motor activity pattern. Thus, although oral perception is essential for denture control, it is well established that the sensitivity of the mechanoreceptors diminishes with age.”[10]

Ivanhoe et al. argues that the denture patient that existed when much of the “classic literature” was published is much different than our denture patients of today. When the initial literature was developed, typical complete denture patients lost their teeth at an early age and were generally young, healthy, and had large residual ridges with firm healthy mucosa. They could expect good functional and esthetic outcomes because their tissues did not need significant facial support from the prostheses and their ridges could withstand comfortable functional loads. He describes the contemporary denture patient as one who presents with very different challenges and will require different maintenance recommendations. These patients are often described as being highly medicated and compromised, often institutionalized, presenting with tissue responses to conventional dentures which are often less satisfactory than the past. He states that because of these challenges these patients are more difficult to manage and treatments are less predictable both esthetically and functionally. These patients often require additional education to aid in acceptance and usage of prostheses.[32]

Zarb states that although health care professionals have devoted much research and attention to organ loss such as mastectomies and hysterectomies, the edentulous state has received relatively little psychological attention. He discusses the multifaceted

physical and psychological challenges facing the edentulous population. He states that because becoming edentulous can be like losing an organ, it should be expected rather than a surprise that many patients fall into the term prosthetically mal-adaptive. The high incidence of maladaptive denture wearing patients has been reported in several studies[33] and has been shown that some patients accepted denture problems as a normal consequence of wearing a prosthesis.[34,35] An analogy can be made with dentists who continue to use their clinical skills to attempt to tackle the problem; when you have a hammer you hit a nail. This connection shows how the true problem for the patient, which is often psychological in origin, can become neglected. He believes that even the initially adaptive patients have a tendency to become maladaptive over time as "degeneration of health during the aging process which changes the patient's neuromuscular control, physical template and environment in which the prosthesis resides."

Several studies have reported significant differences in clinician determined successes and failures compared to patient reported outcomes. No correlations were found between patient satisfaction and the quality of the denture or the quality of the remaining denture- supporting tissues.[30] This review suggests that other than oral factors that may lead to prosthesis incompatibility, psychogenic factors, such as the relationship between patient and dentist, may be important.

The House classification, devised in 1950 by Dr. MM House, has been well known for his evaluation of patients' psychological response to becoming edentulous and their adaptation process to dentures. He classified patients into the following 4 categories: Class I Philosophical: accepts the dentist judgment and instructions with the

best prognosis, Class II exacting: methodical and demanding, ask a lot of questions, with good prognosis, Class III hysterical: emotionally unfit, never happy, worst prognosis, Class IV Indifferent: doesn't care about dental treatment and gives up easily. Gamer et al. suggests that this classification is outdated due to antiquated terminology as well as the lack of attention to how patient's reactions and behaviors are codetermined by those of the dentist.[36] It is suggested that in these 4 classifications only the philosophic patient is ideal for treatment and that all other types of patients present with various obstacles. A new classification is suggested which takes into account the patient doctor relationship which evaluates: 1) the patient's ability to adapt to patienthood, 2) the dentist's response to the patient's adaptation to patienthood, 3)the patient's tendency to unconsciously react to the dentist as if the dentist were someone from the patient's earlier life (transference), 4)the dentist's tendency to unconsciously react to the patient as if the patient were someone from the dentist's earlier life (countertransference), 5) other nonspecific factors.[36]

Carlsson et al. states that although most edentulous patients appear to have benefited from complete denture treatment as is reflected in satisfactory oral and masticatory function, not all complete denture wearers are able to adapt to conventional treatments.[30] For the neurotic patient, less denture satisfaction was found but not a decreased usage of dentures.[37]

The classic article by Koper clearly illustrates the maladaptive denture patient with visual cartoons depicting them in form of various bird species. This article which, although appearing comical, highlights very clearly negative responses that a large population have to dentures.[38] Carlsson states "all who have worked with complete

dentures know that patient satisfaction is not based solely on the technical quality of the dentures."[38] He suggests that psychological factors play a significant role particularly in these maladaptive patients and it may be difficult for the clinician because they come seeking technical advice. He suggest that the ability to listen and communicate effectively as a clinician is the way to help these patients.[39] Visiting the dentist has also been described as a social entertainment for elderly patients particularly in a dental school setting. Continuous denture complaints, given technical success of dentures, may be related to giving these elderly patients something to do. Given all of the challenges facing the edentulous population, depression is a known co-morbidity and therefore it is no surprise that these patients are often challenging for even the most skilled clinicians.[37]

Brunello et al. evaluated complaints in complete denture patients and noted that several authors cited the most frequent complaints with complete dentures to be those related to retention and stability, esthetics, comfort while eating, and the accumulation of food under the appliance. He stated that the factor most affecting the success or failure of complete dentures to be esthetics. He states "When assessing a patient who is experiencing difficulty with his or her dentures, the clinician must critically assess the factors that influence denture acceptance. These factors may provide an explanation as to why there is often a difference between the perceptions of the dentist and the patient of where the difficulty lies."[9] In a review of patients presenting to their clinic with complete denture complaints, Brunello et al. found that 88% of patients had dentures with poor retention, denture bases were either underextended or overextended (86% and 2%, respectively), they formed poor tissue contact (86%), or displayed an

inadequate posterior palatal seal. They also found errors in vertical or horizontal jaw relationships in 94% of patients as well as errors in tooth positions (63%). Studies support that the extent of training of the providing clinician affects the ability to recognize these most common errors in base extension and OVD; senior dental students and general dentists showed less capable of recognizing these errors compared to a group of prosthodontists.[40] As described in the discussion of the comprehensive treatment of the edentulous patient, complete denture therapy may be associated with various co-morbidities and may even exacerbate complications such as mucosal lesions from use of poorly fitting dentures. Brunello et al. states “the dissatisfied complete denture patient in most instances experiences difficulties with his or her dentures due to an identifiable cause and it is recommended that the clinician carefully evaluate the denture for faults before concluding that the patient’s complaint is related to age, gender, or general medical condition.”[9]

As technology is expanding all fields of medicine, it is making a significant impact on techniques used in dentistry today. Carlsson states that the contribution of biotechnology has been apparent in the evolution of implants yet its potential “for adding value to ‘lower-end’ prosthodontic solutions must surely exist and should be pursued with the same vigor as is being carried out for ‘high-tech’ treatments.”[30] The field of digital dentures is expanding rapidly and as continued studies publish similar technical and patient reported outcomes with digital compared to conventional methods of fabrication, these simplified techniques may make fabrication of dentures more affordable and appropriate to reach populations who have limited access to prostheses.

Cooper makes the following recommendations for treatment of the edentulous patient: “organized dentistry must reinforce (1) prevention, (2) the continued monitoring of residual alveolar ridge resorption and related issues of denture function, (3) the continual surveillance of oral mucosal health including the concern for both inflammatory and malignant lesions and development of dentures as therapeutic devices, (4) a rationale for timely re- placement of existing dentures based on defined criteria,(5) clinical responses to maladaptive denture patients be expansive and not solely restricted to the technical aspects of denture construction and(6) the management of edentulism by the continued development of oral implant technology and worldwide enhancement of educational standards concerning oral implant overdenture therapy and denture quality.”[11] Zarb believes that although greater treatment options continue to arise for this population, we cannot abandon this treatment modality due to its affordability and universal application.[27] In summary; dentures provide an affordable, virtually universal prosthesis which has stood the test of town with the downfalls being that it relies on technical skill, patient anatomy and significant requirements from the patient for adaptation and maintenance for prevention of denture induced problems.

3.2 Implant Assisted Treatment Options

3.2.1 Osseointegration

“The objective of stabilizing prosthetic dentitions with endosseous anchorage went through numerous pioneering efforts. However, predictable time-dependent and morbidity free outcomes proved elusive until PI Brånemark’s research on Osseointegration.” [27] In 1982, the Toronto Conference introduced the dental implant and

since 1985 dental implants have been used increasingly to aid treatments for edentulous patients. “It is suggested that the demand for solutions other than conventional removable dentures for the management of the edentulous predicament runs increasingly in parallel with improved standards of living.”[30] The initial use and design of implants was for treatment of the edentulous mandibular jaw with a fixed supragingival reconstruction which was found to have high success rates of >90% after 10 years.[30] Today implants are being implemented in almost every new treatment plan and are even being used in single edentulous spaces to fill a missing tooth even sometimes being restored the same day. Although implants were introduced as a ‘cure’ for mandibular edentulism, time has shown that it is not realistic to expect it to completely remove a mandibular denture as a treatment modality. As discussed, choosing the correct treatment for each patient requires consideration of many unique variables.

Adding implants to a denture has been suggested to reduce mucosal problems such as denture stomatitis due to reducing denture related trauma which results in a decrease in inflammation, as reported by Emami et al. as the risk of denture stomatitis was 4.5 times greater in individuals wearing conventional dentures compared to those wearing implant- retained overdentures.[5] The reduction of residual ridge in complete denture wearers appears to occur in all patients and the etiology of variability in these changes still remains unknown. It is accepted that this process is a “consequence of bone remodeling due to the altered functional stimulus on the jawbone” and it is thought that addition of dental implants modifies the reliance on the residual ridge for support aiding in preservation bone anatomy. Woelfel evaluated ridge resorption as result of

removable dentures and found 63 potential factors while determining that no single factor could explain the variability.[41] Various studies have shown that the placement of dental implants, and use of implant- supported prostheses result in a reduction in bone loss in the edentulous jaw. This is suggested to be caused by an altered functional stimulus to the bone.[39]

The introduction of dental implants has revolutionized prosthodontics and as the dynamics of their use continues we will continue to be challenged by the opportunities and complications they afford us.

3.2.2 Implant Overdenture

The review by Carlsson et al. states that "the two-implant overdenture has gained considerable popularity since its introduction, and based on compelling evidence, has been proposed as the first line of treatment for the edentulous mandible."[30] Zarb states that "The implant supported overdenture appears to combine the best of both options without either method's restrictions."[27] Implants appear to present improvement for most denture patients, yet for the maladaptive patient, implants may change their inability to use a prosthesis at all to wearing a prostheses that is actually functional. The review by Carlsson et al. also found that implant-retained overdentures have shown superiority over complete dentures in realms of patient satisfaction, comfort, chewing ability, social and sexual activities and quality of life with the consideration of food selection not being completely improved.[30]

A randomized control trial performed on complete denture wearers who received either a replacement denture or an implant overdenture reported no significant change in nutrition or weight of the individuals included.[10] As dietary intake is affected by many

factors such as habits, food preference, general health, mobility, culture and cooking skills as well as cognitive impairment and appetite, chewing efficiency alone does not cause a direct change. Food preference is often affected by taste, though this sensation is not isolated, it is made up of a whole experience also encompassing proprioception and smell. It is known that sensitivity to taste declines with age, particularly in patients with Alzheimer's[27], and as this changes it is common for unhealthy preferences to develop for sugar and salt. Xerostomia itself may cause food to taste metallic or salty further causing unhealthy cravings for sugar.[27] Giddon et al. states that "the perception or appreciation of flavors in food is more important than the identification of the taste quality. The appreciation of flavor differences in solid foods, however, is adversely affected by complete dentures."[14] It has been shown through patient reported outcomes that they prefer removal of the palate of a denture, often stating increased gustation as one of their improvements.[42]

Müller lists many functional benefits patients receive with the addition of implants for a denture including a substantial increase in chewing efficiency, as measured by reduced number of chewing cycles as well as increased bite force. Mean masseter muscle thickness was evaluated by means of an ultra sound technique and it was found that patients with implant reconstructions had greater muscle mass compared to those wearing complete dentures, although still being less than dentate individuals.[10] Surface electromyography was also used to record masticatory muscle while subjects chewed agar-based model foods with different fracture strengths and compared to their dentate comparison, denture wearers had masticatory muscle activity that was 2.57 times higher.[43]

Müller states that the majority of the literature refers to mean values for functional evaluations and this may not reflect a true situation for individual patients. The context of patient reported outcomes expands many domains of physical pain, psychologic discomfort, physical disability, psychologic disability, social disability, and handicap. Often the most spoken of improvements patients are seeking with implant-retained overdentures is removing the fear of loss of retention of their dentures in public. The review by Müller found that conventional denture patients retrain from social activities including singing in a choir, sports activities, socializing with family and friends, eating in restaurants, as well as neglect intimate relations.[10]

As described, attention must be paid to the uniqueness of the etiology of tooth loss for each patient as a consideration for future maintenance required.[11] The initial disease factors which caused edentulism will often remain a complication for the patients' maintenance and as such a removable prosthesis which can be cleaned outside of the mouth becomes a valuable. Compared to a conventional denture, patients must make extra efforts to maintain their implants intraorally and studies have shown greater success with hygiene around solitary abutments compared to implants splinted with a bar.[44–46] Hygiene is significantly more difficult with full fixed prostheses as prosthetic junctions are often closely approximating the tissues to aid in esthetics and prevent air gaps affecting phonetics. Particularly for patients who have lost dexterity, fixed prostheses are not recommended.

Implants for dentures have shown such success that the mandibular overdenture is now recommended as the standard of care treatment in many countries.[47] Although implant placement appears biologically universally applicable in the parasymphaseal

mandible, the same cannot be said for the edentulous maxilla. Additional complications for maxillary implant overdentures are summarized in the following: esthetics, phonetics, bone resorption in relation to residual soft tissue, poor bone quality often being Type III in most locations, as well as poor residual bone posteriorly to allow for desired anterior posterior spread of implants.[48] Implant survival and success rates are lower in the maxilla due to poorer bone quality, yet improvements in biotechnology of implant design, away from machined surface to a moderately rough surface, have demonstrated higher survival rates.[44] Success rates have risen such that implant placement in the maxilla, although challenging, has now become a reliable treatment.

Placement of implants in the edentulous maxilla has often been described as difficult not solely due to poor bone quality but also due to resorption patterns which often leaves the residing bone far from the desired restoring tooth positions. An advantage with overdentures compared to fixed prostheses is that more patients may have available bone in regions needed for placement as Meriscke et al. states “the full congruence of tooth position on the prosthesis and implant location is not necessary for overdentures.”[48] For overdentures, implants are ideally placed to reduce a cantilevered prosthesis with a proper anterio-posterior spread and as parallel as possible if using unsplinted abutments to allow for passivity of the prosthesis upon removal. As these implants have a given ‘freedom of emergence’ from the tissue to lie underneath the denture, less stress is place on the surgeon to line up each implant position with a particular crown as would be needed for a fixed prosthesis. “A removable implant design may circumvent extensive and costly augmentation procedures required for fixed

restorations as more than a third of patients are unwilling to undergo autologous grafting even from an intraoral donor site."[44]

Carlsson et al. suggests that implant placement for use with an overdenture still remains an economic obstacle for many patients compared to costs of a conventional denture as they found that implant overdentures cost between two and three times that of complete dentures.[30] Although the initially higher fee may be prohibitive, it is suggested that after review of the costs of maintenance combined with patient satisfaction of quality of life, over a 10 year time period, the cost-effectiveness of implant overdentures makes them the treatment of choice.[30] Compared to a fixed prosthesis, the cost related to maintenance, has shown to be less expensive for the mandibular implant overdenture.[30,49] Given the success rates for implants in the mandible to support dentures as well as the affordability of often using only two implants for this significant improvement, Mericske-Stern et al. states that mandibular overdentures are a true alternative to fixed prostheses in terms of economics and time-saving procedures.[48] Further evaluation is needed to compare implant overdentures to implant fixed prostheses regarding cost and maintenance in the maxillary arch.

Although costs for maintenance are shown to be lower for implant retained overdentures compared to implant supported fixed prostheses, there is still a significant increase in maintenance of overdentures compared to their conventional denture counterparts.[50] Carlsson et al. concluded "While there is compelling evidence that implant- retained and/or -supported prostheses are in many ways superior to conventional complete dentures and would represent the standard of care for edentulous individuals, the majority of them are poor and will never be candidates for

implant therapy; at the very best, they can hope for well-functioning complete dentures."[30]

The recent Academy of Osseointegration 2014 Summit for treatment recommendations of the edentulous maxilla made the following conclusions for application of clinical guidelines: a maxillary IOD offers a stabilized removable solution for the edentulous maxilla that provides increased patient satisfaction and oral health QoL, a higher failure rate is experienced with machined implants, four to six implants are widely applied in successful cohort studies, when four or less implants are used for max IODs, unsplinted designs have a higher implant/prosthetic failure rate than splinted implants. They also set the following guidelines for treatment with a maxillary implant overdenture: When considering a max IOD design, the practitioners' team and the patient must understand the importance of long-term regular maintenance care, in the diagnostic phase, clinicians must identify systemic, local (e.g., vertical space requirements) and patient-based factors to best select the adequate treatment regimen, the max IOD prosthesis should be designed to be maintainable, retrievable, repairable, or replaceable, placing a minimum of four implants with a wide antero-posterior distribution of optimal support is recommended. Consider more implants when associated risk factors are present. Implants less than 10 mm in length challenge initial stability but implants with moderately rough surfaces may provide similar success rates irrespective of implant length, in general, both splinted and solitary anchorage systems are advocated. Maintenance may be higher for solitary attachments. Increased soft tissue inflammation has been reported under bars, and a palateless design offers better patient satisfactions.[44]

In summary, compared to a conventional denture, the implant overdenture has shown significant increases in patient satisfaction while being cleansable and cost effective.

3.2.3 Implant Supported Fixed Prosthesis

In a review, Meriscke et al. describes that both fixed and removable implant treatment options can easily be offered in the edentulous mandible while the edentulous maxilla presents anatomic-morphologic and esthetic challenges which must be highly considered before choosing a fixed prosthesis. Although edentulism is declining, there remains a younger population who has terminal dentition and is not ready to transition into removable prostheses. These patients request rehabilitation particularly with fixed prostheses and expect a restoration similar to their old dentition. He describes that patients asking for fixes prostheses in the maxilla often times have opposing natural dentition and their choice for fixed prostheses is often based on psychological opposition to a removable prosthesis. It was recommended to consider the following: anatomic and morphologic structure of the maxilla, bone quantity, and esthetic considerations: facial support, tooth length, soft tissue management, ease of repair, and economics.

Hard tissue quality and quantity must be appropriate for placement of four or more implants required for fixed maxillary reconstruction, as well as soft tissue architecture for esthetics and cleansability. Meriscke et al. states that clinical experience shows favorable soft tissue management around single implants yet the literature for a well contoured border around implants of an entire dental arch is still in its infancy. He described the phonetic problems that have been reported with fixed prostheses

compared to overdentures, in the case where implants are placed too far facial or lingual without proper consideration of the emergence of the final fixed restoration.

Particularly important for esthetics in the edentulous maxilla is to use the prosthesis to replace any lost anatomy which includes teeth, bony architecture, as well as soft tissue contours and lips.[51] Secondly attention must be paid to placing the prosthetic junction below the high smile line for the patient which for patients which a high smile may require further bone removal for a fixed prosthesis. Meriscke et al. describes that the inter-maxillary distance between the incisal edge of the lower teeth and the contour of the maxillary jaw is an important relationship to properly support the soft tissue and that it should not exceed 15 mm. If this amount is excessive, the teeth may be elongated to compensate and does not present the proper facial support. He suggests that a low lip-line is advantageous for fixed prostheses as it is easier to hide the prosthetic junction without having to remove additional bone more apically. Figure 2, taken from Table 7.1 created by Meriscke et al., provides a list of diagnostic criteria to consider for choosing between a fixed or removable prosthesis for the maxilla.

Table 7.1. Summary: diagnostic criteria for the maxilla

Extraoral	Fixed	Removable	Intraoral	Fixed	Removable
Lip-line	Low	High	Ridge (shape)	Vertical	Buccal inclination
Tooth display	Little	Distinct		Convex	Buccal concavity
Facial support, lip support	No need	Necessary	Intermax. dist.	≤10 mm	>15 mm
			Intermax. relation	Neutral	Skeletal III
				Deep overbite	Crossbite
			Mucosa	Thick, keratinized	Thin, mobile

Figure 2: Diagnostic Criteria for the Maxilla

In the review by Zitzmann et al, it is stated that if proper treatment planning is followed prior to the placement of implants for the edentulous maxilla, one can avoid

compromised solutions. He discusses that attention must be paid to a full examination of the patient which includes intraoral, extraoral, and radiographic factors as well as patient preference and psychology related to treatment; this is depicted in tables created by Zitzmann et al. shown in Figures 3a, 3b, and 3c.[52]

Table II. Checklist for implant treatment: Patient's history

Superstructure	Fixed implant prostheses	Removable overdenture	
		With reduced palatal coverage	With full palatal coverage
Patient's related factors			
Patient's preference	Preferred	2nd choice	3rd choice
Phonation	More problems	Fewer problems	Fewer problems
Excessive gag reflex	Fewer problems	More problems	More problems
Ability to perform oral hygiene	More demanding	Easier	Easier
Economics	More expensive	Less expensive	Less expensive

Figure 3a: Patient's History

Table III. Checklist for implant treatment: Extraoral examination (based on an acceptable existing prosthesis or an ideal wax-trial denture)

Superstructure	Fixed implant prostheses	Removable overdenture
Extraoral factors		
Facial support:	☐ Unnecessary	☐ Needed (evaluated with and without prosthesis)
Esthetic plane:	☐ Convex profile	☐ Concave profile
Maxillomandibular relationship (Angle class):	☐ Class I/II	☐ Class III (to be compensated)
Lip support	☐ Entire lip thickness displayed	☐ Trapped, thin upper lip
Smile line (determined during repose/speech/expanded smile)	☐ Low	☐ Average ☐ High (alveolar ridge visible during speech)
Vestiblar space:	☐ Little	☐ Increased during smiling
Horizontal tooth display:	☐ 6-10 teeth (no/1 cantilever possible)	☐ 10-14 teeth (posterior soft tissue support possible)
Length of the upper lip (subnasal to philtrum)	☐ Long (26-30 mm) ≈ 0.9 mm of upper central teeth visible ☐ Average (21-25 mm) ≈ 2.2 mm of upper central teeth visible	☐ Short (16-20 mm) ≈ 3.4 mm of upper central teeth visible

Figure 3b: Extraoral examination

Table IV. Checklist for implant treatment: Intraoral examination (based on an acceptable existing prosthesis or an ideal wax-trial denture). Determine **free-way-space** and **incisal edge position** (touching the vermillion border of the lower lip during "F" sound)

Superstructure	Fixed complete denture	Removable overdenture
Intraoral factors		
Mucosal quality:	☐ Keratinized ☐ Nonmovable	☐ Nonkeratinized ☐ Movable Soft tissue graft feasible: ☐ Yes ☐ No
Mucosal quantity:	☐ Thick (molding possible)	☐ Thin
Bone quantity:		
Ridge palpation buccal and crestal:	☐ Buccal (convex), crestal (rounded, wide)	☐ Buccal (concave), crestal (thin, sharp) Bone graft feasible: ☐ Yes ☐ No
Incisal papilla position:	☐ Palatal	☐ Crestal ☐ buccal
Crown-bone relationship/interarch space		
Length of the clinical crown: (mean length of central incisors 10.5 mm)	☐ Optimal (minimal vertical resorption)	☐ Too long (to large vertical space) Pink porcelain accepted: ☐ Yes ☐ No
Tooth size to arch size discrepancy:	☐ No	☐ Yes
Speech disruption (phonetic zone):	☐ No	☐ Yes (needs adaptation of S-ridge)
Bone quality: (approximately assessed from computed tomographic scan)	☐ Type I (solely compact) ☐ Type II (dense trabeculated/thick corticalis)	☐ Type III (dense trabeculated/thin corticalis) ☐ Type IV (porous spongiosa)

Figure 3c: Intraoral Examination

Another article by Jivraj et al. states that evaluation of the patient's amount of maxillary resorption allows a landmark to determine if a fixed or removable prosthesis is warranted. It is recommended to use a trial denture, when the opportunity allows, to evaluate lip support with and without a flange. They suggest evaluating the movement of the upper lip during speech and smiling; "Tjan et al. described the average smile as having the position of the upper lip such that 75% to 100% of the maxillary incisors and interproximal gingiva are displayed. In a high smile line additional gingiva was exposed and in a low smile line less than 75% of the maxillary anterior teeth are displayed."[53] As it is a requirement that the patient have access to the residual ridge form hygiene, it is imperative that this evaluation be completed ahead of time as a flange cannot be added back to a fixed prosthesis.

3.2.4 Conus: Implant Supported Removable Prosthesis

As the implant overdenture has been termed “a true alternative to fixed prostheses in terms of economics and time-saving procedures,”[48] the ‘Conus’ prostheses, popularized by ATLANTIS (DENTSPLY Implants, Mannheim, Germany), appears to offer yet another successful treatment option. This treatment combines the benefits of being removable in terms of allowing a flange to support soft tissue when needed as well as oral cleaning, while having the feel of retention similar to a fixed prosthesis. These prostheses are considered implant supported as they are retained by 4 custom milled metal abutments, properly tapered to one another, allowing significantly more support and retention than resilient abutments such as locators. The copings which align with the abutments are either incorporated into a metal bar substructure which becomes encased in acrylic or are cemented into a zirconia milled prosthesis.

A randomized control trial was performed by Cepa et al. to evaluate implant survival, peri-implant tissues, prosthetic maintenance as well as patient satisfaction comparing 2 types of unsplinted attachment systems.[54] Twenty-five patients had 2 implants placed in the parasymphyseal mandible to be restored with a mandibular overdenture and were randomly chosen to be restored with either two prefabricated resilient ball attachments (ANKYLOS, DENTSPLY Implants, Mannheim, Germany) or two rigid prefabricated conus attachments (ANKYLOS SynCone, DENTSPLY Implants, Mannheim, Germany).

Clinical and radiographic follow-up was performed up to 3 years after prosthesis delivery resulting in implant survival of 100% and no difference in peri-implant measured parameters. Inacceptable retention was found to be high for both groups, with several of

the conus patients dropping out due to lack of satisfaction. Patients were found to have initially high satisfaction with their prostheses however this level of satisfaction dropped with successive required follow-up maintenance visits. The author suggests that the high dissatisfaction may have been related to the hardly adjustable retention system. A particularly positive finding was that even elderly patients appeared to adhere to the hygiene instructions which resulted in lasting success of peri-implant tissue health. The authors state that the patient satisfaction and economy of the attachment systems should continue to be questioned and that for the conical attachment, the manufacturer recommends using four intraforaminal implants.

One concept which requires further investigation is the use of a rigid connection combined with soft tissue support such as what was used in this study. As the tissues are movable, yet the abutments remain rigid, as in the conus system, majority of the masticatory force is directed to the rigid implants and components resulting in stresses which may cause fatigue and eventual fracture within the rigid system. This was seen as a fracture of one of the conus abutments in this study and the authors suggest that this design is particularly contraindicated in patients with bruxism. They recommend that a rigid bar may be a more favorable option for stress distribution onto the implants. Few studies exist for the designed protocol for four intraforaminal implants and further investigations are recommended.[54]

4. Oral Health Related Quality of Life Measures (OHRQOL)

Zarb noted that “Patient perceptions and responses to health care measures are now regarded as an integral part of the clinical decision-making process.”[27] It is well known that a clinician’s technical acceptance of a prosthesis does not equate to patient

acceptance of their prosthesis.[55,56] Because we now recognize the importance of patient reported outcomes, reliable measures have been sought to quantify differences in treatments.

Strassburger et al. reviewed the development of instruments assessing patient-centered outcomes and found initial investigations to have low levels of evidence. The first important study, although retrospective, was done by Carlsson et al. in 1967 which included psychosocial aspects of wearing complete dentures. Further quality studies were developed by Smith and Sheiham in 1979 which marked the first time the relationship between unsatisfactory prostheses was related to impacts on daily life. Cushing et al. in 1986 included the social and psychologic factors in his epidemiology publication where it was found that "existent indices, such as DMFT, were ineffective for expressing the subjective oral health experiences of patients. In this study, the authors devised "socio-dental indicators" for evaluating the effects of dental diseases."[57]

Strassburger et al. continued to find additional indices that developed such as the Geriatric Oral Health Assessment Index (GOHAI) in 1990 by Atchison and Dolan and the Dental Impact Profile in 1993 developed by Strauss and Hunt, which consisted of 25 questions about perceived value of oral health. The review then highlighted that "one instrument has prevailed in terms of frequency of use: the Oral Health Impact Profile (OHIP), introduced by Slade and Spencer in 1994. It was based on Locker's concept of how oral health affects quality of life, which in turn is an adaptation of the 1980 World Health Organization's International Classification of "Impairments, Disabilities, and Handicaps."[57] Strassburger et al. states that since this been widely used in multiple

contexts. Several versions have been validated including the OHIP-20E. This shorter form is designed specifically to evaluate patients with removable prosthetics.

In 1994, Slade and Spencer published the Oral Health Impact Profile (OHIP) questionnaire that quantified the adverse impact of oral conditions on quality of life. They describe the process of deriving a set 49 unique statements, which describe the consequences of oral disorders, were initially derived from 535 statements obtained from interviews with 64 patients.

"The OHIP offers a reliable and valid instrument for detailed measurement of the social impact of oral disorders and has the potential benefits for clinical decision making and research."[58] It is stated that further benefits can be gained from assessment of the social impact of dental treatments and 3 clear uses for this data were recommended. First, they suggest that the assessment of priorities of care can be improved to direct dental programs toward the most dysfunctional conditions. Secondly, these measures can improve the understanding of oral health related behaviors of patients as it is known that individuals perceived impact of conditions has been identified as motive for preventative care seeking behaviors. Thirdly, understanding of the patient reported outcomes help our profession advocate for oral care. It was stated that by describing these outcomes in a more concrete way helps to draw attention to the importance of oral disease as part of the general health. They argue that oral health becomes much more impactful to policy makers when reduced activity and days of disability caused by oral conditions is compared with those of respiratory disease, genito-urinary disorders and cancers, as was done by Reisine in 1998. They state that this relation to social impact was also done by Spencer and Lewis 1988 when they used data from the

Australian Health Survey and calculated 646,000 days lost from school and 1.1 million lost from work in 1983.

A particular challenge described by Slade et al. attempting to create an index reflecting a hierarchy of social impact was in identification of range of relevant events and finding a means of combining the frequency of those events into an ordinal index. Through methods comparable to was done in the development of the indices of general health status by Gilson et al. in 1975 and Hunt et al. in 1986, Slade et al. created a conceptual model and associated weights. The OHIP 49 (Appendix A; adapted from Erkapers et al.)[59] was then created based on a conceptual model by Locker shown in Figure 4; adapted from Slade et al.[58] At the time of creation of OHIP 49, functional limitation was the most frequent domain among edentulous (69%) while physical pain was the most prevalent domain for dentate (71%).[58]

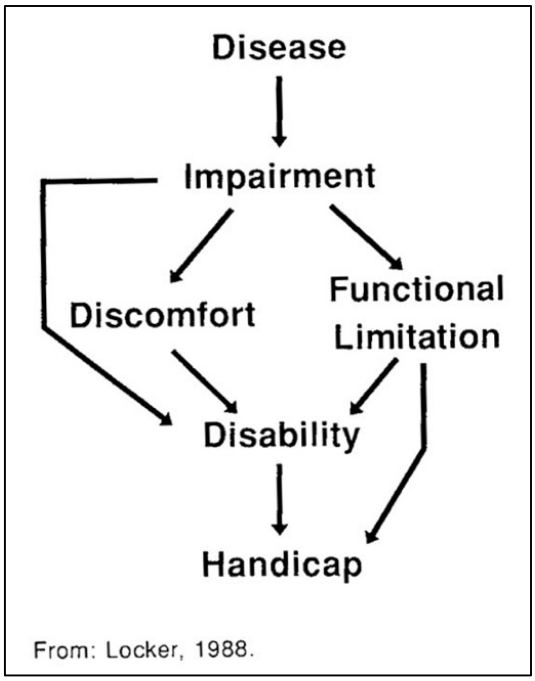


Figure 4: Locker's model of Oral Health

In 1998 Slade describes that traditionally longitudinal oral epidemiological studies have measured change using clinical indices that rely on objective measurements made by carefully trained and calibrated examiners, such as a measure like periodontal indices. “Motivation for measurement of both negative and positive changes in health status has arisen as it is clear that people’s subjective assessment of their own health status is a major independent predictor of mortality, morbidity, and health care utilization.”[60]

He reported on methodological issues that have arisen in assessing change in OHR-QOL of a longitudinal study using the OHIP. One of the challenges with a two-way analysis, such that some things can increase and some decrease, “quantitative analyses cause improvements and deteriorations to cancel, and analysis of mean OHIP

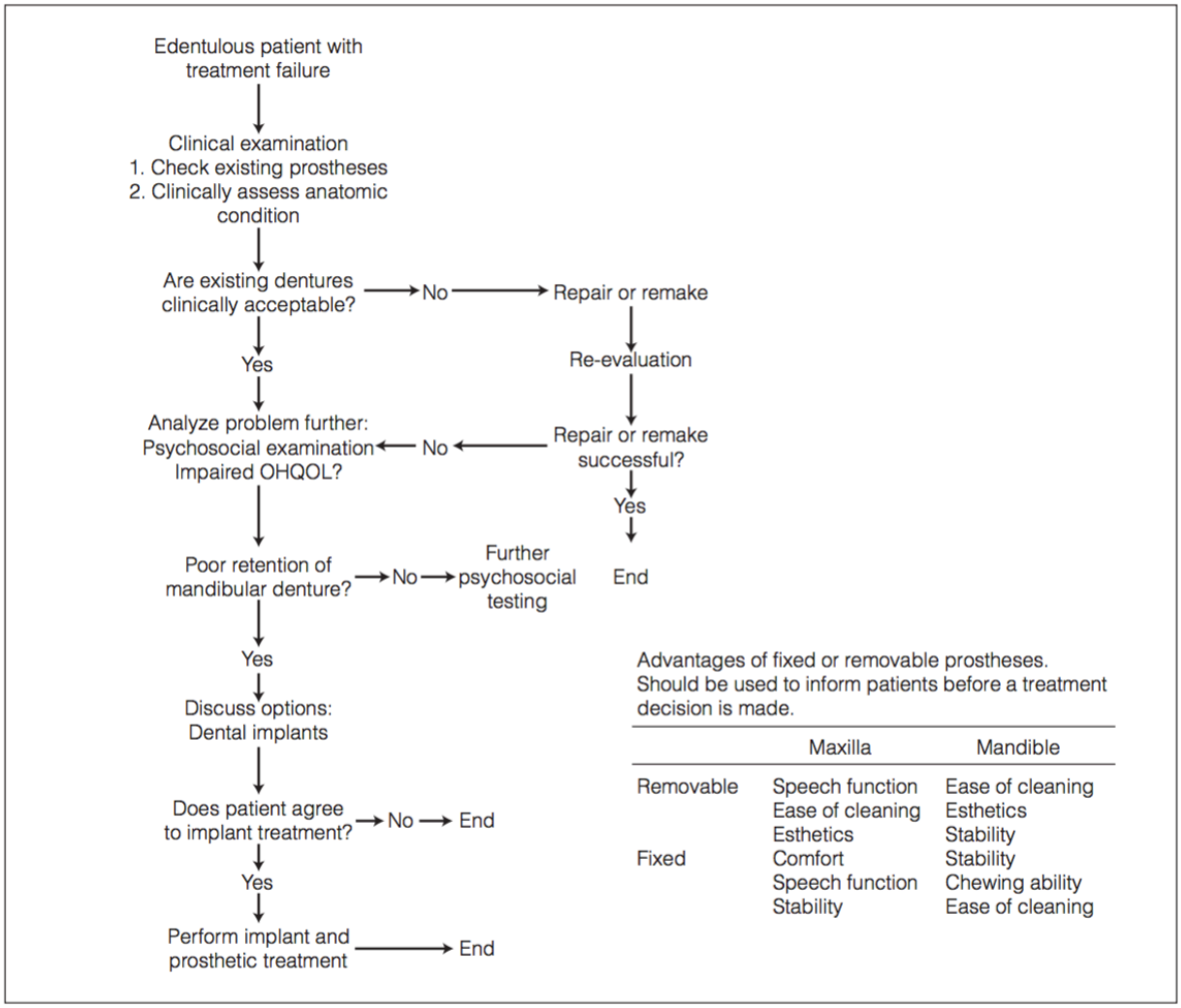
scores may create a spurious impression that change in OHRQOL did not differ between dental visit groups."[60]

He states that a key limitation of quantifying these scores may create the appearance of equivalence between a group in which all individuals have no change in impact and a second group composed equally of individuals with the same magnitude but opposite directions of change in scores. This can be imagined in a dental setting using tooth loss as an example; tooth loss may worsen the quality of life for some individuals due to lack of function others in significant pain due to infected teeth may see tooth loss as an improvement.

For this reason, he recommends that clear hypotheses must be created to attempt to separate contrasting affects. He continued by discussing that further changes in mean OHIP scores were found to be masked by regression to the mean, and recommended several methods to control for this statistically. He states "The major issues that have emerged from this analysis are: 1. When change in quality of life is measured categorically, some presumed risk factors appear to be predictors, simultaneously, of improvement and deterioration in quality of life, 2. These simultaneous and contrasting effects occur within groups, presumably because some hypothesized risk predictors, such as tooth loss, may worsen quality of life for some individuals, but improve quality of life for others, 3. However, it is possible that these simultaneous and contrasting effects occur within individuals, such that a single event (for example, tooth loss) could improve some aspects of an individual's quality of life while worsening others, 4. When analyzed quantitatively, patterns of change in quality of life may be masked by this phenomenon of simultaneous and contrasting effects and

consequently, subgroups (such as people in this study with different patterns of dental visits) may appear spuriously to have equivalent outcomes, 5. Since this quality of life measure is prone to within-subject variation and measurement error, comparisons of quantitative scores between sub- groups may also be masked by effects of regression to the mean.[60]

The review by Strassburger et al. states that the majority of currently published dental studies neglected to use the existing well- developed questionnaires such as the OHIP, and rather came up with unique non-standard ways of questioning patients. The authors suggest that for patient reported outcomes to become validated and applicable to clinical practice, comparable practices must be followed. “Oral health–related quality of life (OHQOL) has been defined as a more comprehensive multidimensional assessment of the consequences of prosthetic rehabilitation.”[57] In summary, based on findings, Strassburger et al. proposes a procedure, in Figure 5, for managing edentulous patients who complain about their conventional complete dentures which allows the clinician to determine the most appropriate solution for retreatment. Guckes et al. similarly describes an algorithm for addressing the edentulous patient with focus on the outcome assessment for each treatment strategy which includes longevity, physiological impact, psychosocial impact, as well as economic impact for the patient (Figure 6, adapted from *Figure 1* Guckes et al.).[61]



Advantages of fixed or removable prostheses. Should be used to inform patients before a treatment decision is made.

	Maxilla	Mandible
Removable	Speech function Ease of cleaning Esthetics	Ease of cleaning Esthetics Stability
Fixed	Comfort Speech function Stability	Stability Chewing ability Ease of cleaning

Figure 5: Model of a clinical pathway for an edentulous patient with failed conventional

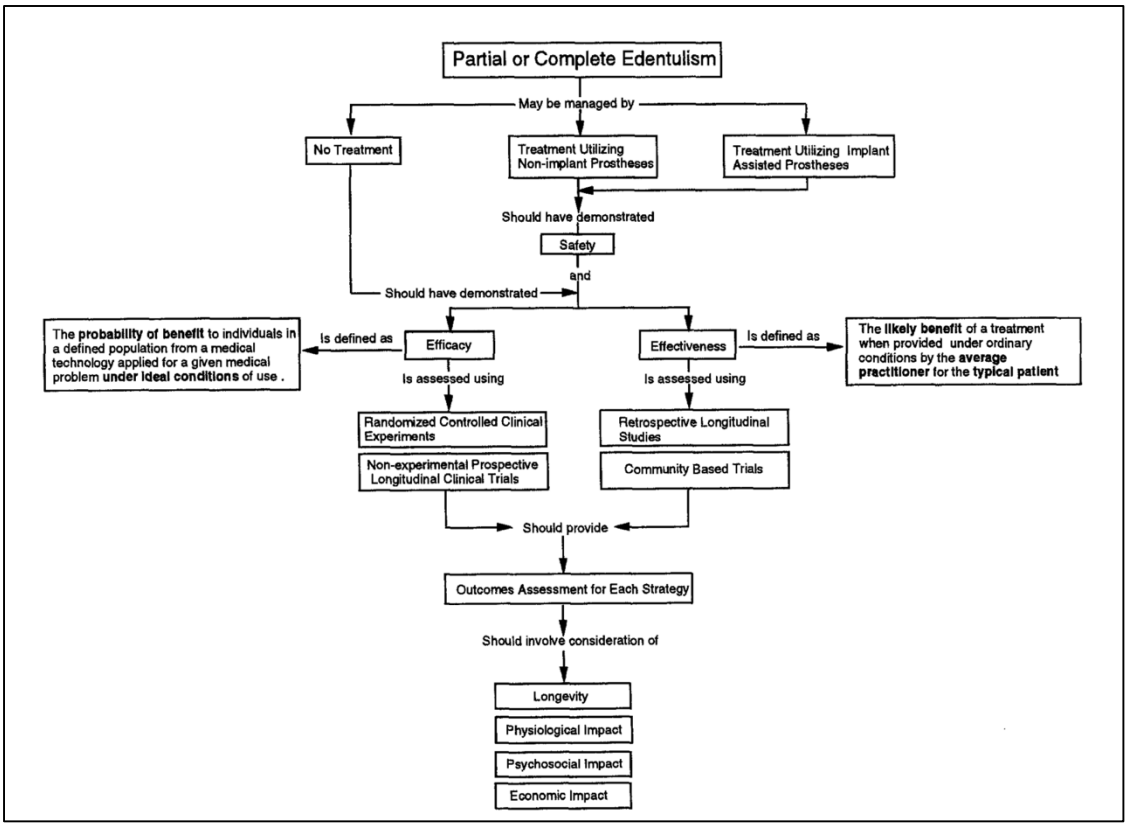


Figure 6: Concept map for management of edentulism

A review by Allen et al. summarized that a number of studies comparing conventional dentures with implant-retained overdentures suggest that oral health status is improved with implant placement.[62,63] To further investigate this, Allen et al. performed a longitudinal study of 103 subjects to evaluate psychosocial well-being of treatment with complete dentures and implant prostheses. They separated subjects into various treatment groups and also included a group of dentate subjects as comparison. The treatment groups included: (1) an implant group, where subjects were edentulous/edentate in one jaw and requested and received implants to retain an oral prosthesis, (2) subjects edentulous/edentate in one jaw requesting implants but who

received conventional dentures, (3) edentulous subjects requesting replacement of their dentures by conventional means.

It was found that subjects who came to the clinic requesting implants had the poorest oral health prior to treatment, edentulous subjects who received the treatment of their choice reported significant improvement in their oral health related quality of life and dentate older adults reported the best quality of life outcomes pre- and post-treatment.[62] The group of patients who requested implants but only received new conventional prosthesis were determined to remain at a lower satisfaction level. The authors suggest two possible reasons for this: (a) these subjects did not receive their treatment of choice, and were therefore biased in their opinion of conventional dentures, and (b) their complaints could not be rectified using conventional prosthodontic techniques, even when treatment was provided by a specialist.[62] Continued evaluation of patients reported outcomes in a systematic manner may afford clinically applicable treatment recommendations in the future.

5. Comparable Studies

In 2014, the Academy of Osseointegration gathered a task force of over 120 of the world's leading scientists and clinicians to evaluate current treatment concepts maxillary edentulism. This group was challenged to review and analyze data involving all aspects of restoration of the edentulous maxilla to help formulate clinical guidelines based on sound published evidence and accepted treatment approaches. One of the guideline articles published in this report was a systematic review conducted Sadowsky et al. on maxillary implant overdenture treatments. They found that as the incidence of edentulism "has been shown to occur earlier and more frequently in the maxilla than in

the mandible (40% vs 27% in patients > 65 years of age)", maxillary implant-retained overdenture has gained popularity as a treatment option.[44] The technical considerations and recommendations were discussed earlier, and attention will now be paid to the patient reported outcomes.

After appropriate review, studies including a total of 530 patients treated with max IOD prostheses between 1993 and 2014 were included. They found that a range of 1 to 10 implants were used with most using 4 to 6 implants as well as a variation in using prefabricate vs. milled abutments and bars, splinted and unsplinted designs, as well as full palate and palateless dentures. Sadowsky et al. states "Despite the heterogeneity of the studies included, in terms of sample size, follow-up periods, implant macro- and microstructure, number of implants, prosthetic design, anchorage system, and method of data collection, trends were identified assisting the practitioner in treatment planning for max IODs." These were discussed in *Implant Overdentures 3.2.2.*

Zitzmann et al. presented treatment outcomes comparing fixed and removable implant-supported prostheses for the edentulous maxilla. Using the visual analog scale for patient assessment, it was determined that patients treated with a fixed prosthesis and removable prostheses, as long as it was implant retained, had similar satisfaction and showed significant improvements in reported self-esteem. Results indicated that patients in the overdenture category experienced greater increases in satisfaction from pretreatment to post treatment, however no standardized pre-treatment oral condition was required for inclusion of the study. After being asked to indicate preference for either the fixed or removable treatment, 80% chose to receive the fixed restoration.

These patients then underwent further discussion with the clinician, reviewing recommendations with comprehensive consent. This process resulted in 38% of the initial 80% choosing to then accept a maxillary implant retained overdenture.[29]

Zembic et al. treated 21 maxillary edentulous patients with 2 implant retained over dentures and compared patient satisfaction before and after removal of the palate of the prosthesis using the VAS questionnaire and OHIP-20E questionnaire. Prior to implant placement, patients received either a reline of their existing denture, if esthetics were satisfactory, or new conventional dentures then a pre-treatment was evaluation completed with indicated questionnaires. A within-subject comparison was completed after restoring the maxilla with two implants with a full palate implant retained overdenture, which was then converted to a palateless implant retained overdenture, at a 2 month time period. The authors found that with regard to all 7 OHIP domains, the implant retained overdenture, with and without palatal coverage showed improvement for most parameters of evaluation except for cleaning ability, comfort, and esthetics. They found that a better perception of taste was reported for the palateless design. Patients were given the option of keeping the prosthesis palateless or placing a palate back into the middle and although 16 patients chose an open palate, five selected palatal closure. This corresponds to results obtained by Al-Zubeidi et al. which found that 80% of patients preferred the palateless design.[64] The author suggests that no differences were reported for esthetics as the esthetic challenges presented in the initial unsatisfactory conventional denture was rectified in the new conventional dentures prior to implant placement. Regarding the cleaning ability, all patients had previously been edentulous for a period of time and had been accustomed to a simple extra-oral

cleaning protocol of their prosthesis, therefore the intraoral additional cleaning efforts were increased with the addition of implants.

Evidence for treatment in the realm of patient reported outcomes appears to present the following conclusions: a) Patients have demonstrated preference for reduced palatal coverage in the area of esthetics and taste, Patients appear to report similar satisfaction with fixed and removable implant prostheses, and patients who receive the treatment of their choice are more satisfied.[62]

The following recommendations were made for future evaluation using patient reported outcomes; a pretreatment questionnaire is important to properly compare patient reported evaluation before and after prosthetic rehabilitation, post treatment patient outcomes are best evaluated after allowing a proper adaptation period of 2 to 6 months.[62] Two months has been defined as an adequate time period for patients to adapt to and therefore evaluate their new dentures as was done in other studies comparing conventional and implant retained overdentures.[34,63]

MATERIALS AND METHODS

1. Study Design

This study was a prospective observational study, designed to evaluate changes in quality of life of maxillary edentulous participants with implant retained palateless overdentures throughout stages of rehabilitation. The research protocol was approved by the University of North Carolina Institutional Review Board (#16-0521). The study protocol and purpose were clearly explained to potential participants during the recruitment process. Those who volunteered to participate provided written informed consent obtained prior to enrolment.

Table 1: Treatment Protocol

Time (Weeks)	Prosthesis Evaluation	Visit	Procedure	Consent	Exam	Photos	Impression	CBCT	PO	OHIP-49 Forms*	Radiograph
0		1	Treatment Planning Visit	x							
		2	General Exam	x	x	x	x			x	
		3	Final Impressions for Interim				x				
		4	Bite Registration				x				
		5	Esthetic Try-In			x					
1-2	x	6	Denture Insertion and CBCT					x	x		x
2-3		7	1 week post insertion assessment		x				x		
3-4	10 weeks	8	Guided Implant Placement						x		x
4-5		9	Post surgical assessment		x				x		
11-12	x	10	Insert Overdenture (Locators attached in interim denture)			x			x	x	
	10 weeks	11	Impressions for PLOD						x		
21-22	x	12	Insertion of PLOD						x	x	
	10 weeks	13	2 weeks post insertion of PLOD						x		
31-32	x	14	2 months post insertion PLOD							x	
Total = 31 -32 weeks											

2. Patient Selection: Inclusion and Exclusion Criteria

Inclusion criteria required that adult participants: be requesting implant placement due to dissatisfaction with their existing maxillary conventional denture, have received a maxillary conventional denture from the UNC School of Dentistry within the last 10 years; be ASA Class I or II; have no history of IV bisphosphonate use contraindicating dental implant placement;) if diabetic, controlled (HbA1C ≤ 7),[65] smoke ≤10 cigarettes daily;[66] maxillary edentulous and wearing conventional dentures for a period of at least 6 months; radiographic evaluation with panoramic x-ray (P-11) shows apparent

adequate bone volume in the maxilla to place 4 implants without the necessity of sinus augmentation or hard and soft tissue grafting.

A convenience sample of 19 maxillary edentulous participants was accepted for initial recruitment of fabrication of a new maxillary denture based on their presentation of a panoramic or CBCT radiograph taken within the last 6 months. Initial clinical and radiographic exam confirmed appropriate inclusion in the study. All maxillary edentulous treatment options offered at UNC School of Dentistry Prosthodontic Clinic were reviewed with the patient which includes; i) augmentation of the existing denture through relining or rebasing if the prosthesis allowed, ii) remaking the existing conventional denture if apparent esthetic and functional inadequacies are present to be improved upon, iii) placement of 4 implants for an implant overdenture with or without palatal coverage, iv) placement of 4 or more implants to facilitate an implant supported fixed prosthesis given the patient had available bone and restorative space. Participants were informed of all risks and benefits of treatment choices and if implant overdenture was determined as the treatment of choice, the patient was consented into the study.

Table 2: Recruitment Criteria

Inclusion	Exclusion
ASA Class I and II	ASA III
Maxillary edentulism and wearing a conventional prosthesis for at least 6 months	History of IV bisphosphonate use
Patients requesting implant placement due to dissatisfaction with conventional prostheses	Requiring bone augmentation for implant placement
Adequate bone volume for placement of 4 implants	Uncontrolled Diabetes (HbA1c >7)
Willing and able to undergo prosthetic and surgical treatments	Smoke more than 10 cigarettes daily
	Pregnant or plans to become during duration of study

All participants presented with dentures which could be improved upon functionally or esthetically therefore after adequate bone was determined and the patient choose a 4 implant overdenture as a final prosthesis; new conventional dentures were fabricated according to proven standards as was done by Zembic.[34]

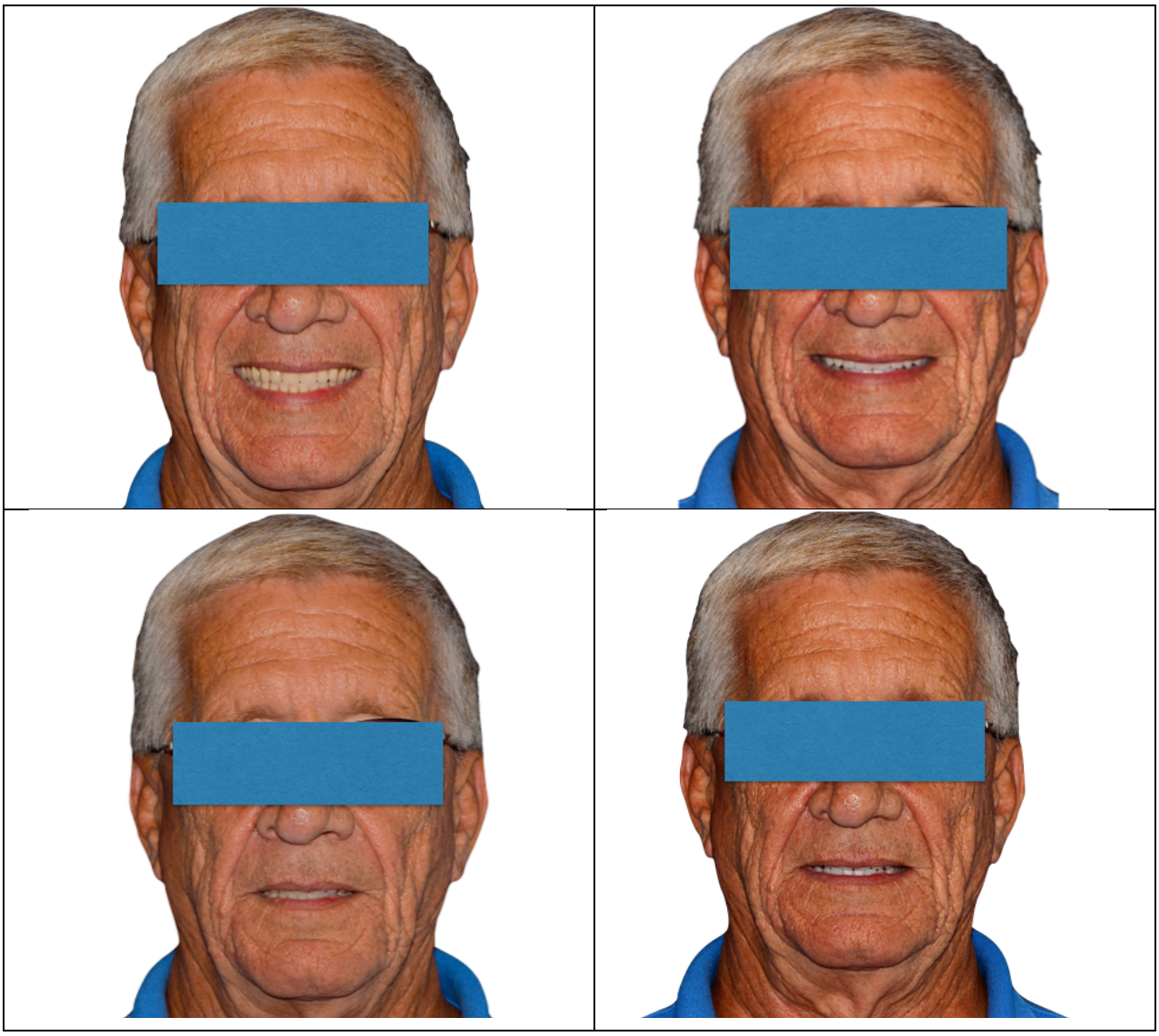


Figure 7: Old and New Conventional Dentures

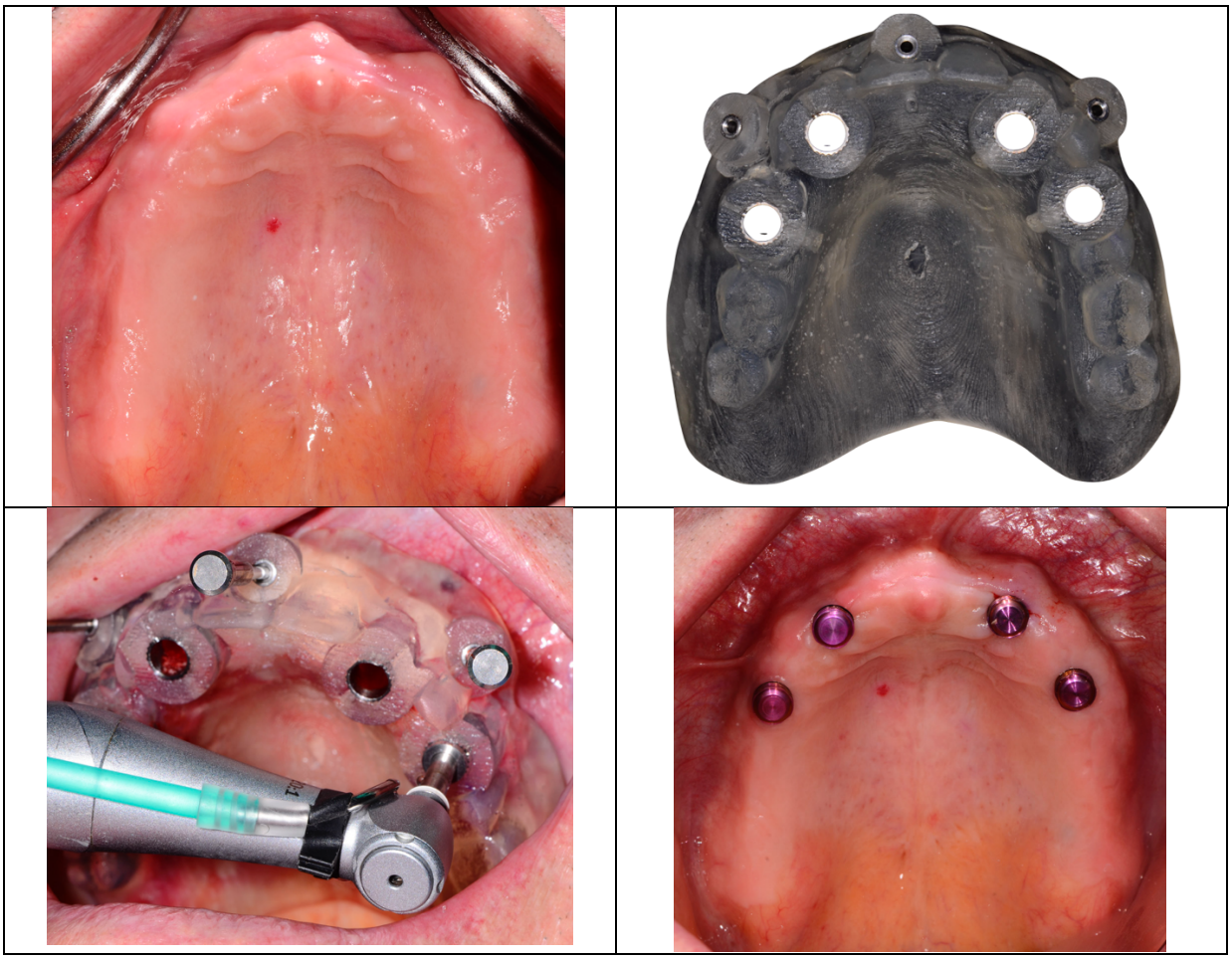


Figure 8: Mucosa-borne Guided Implant Surgery

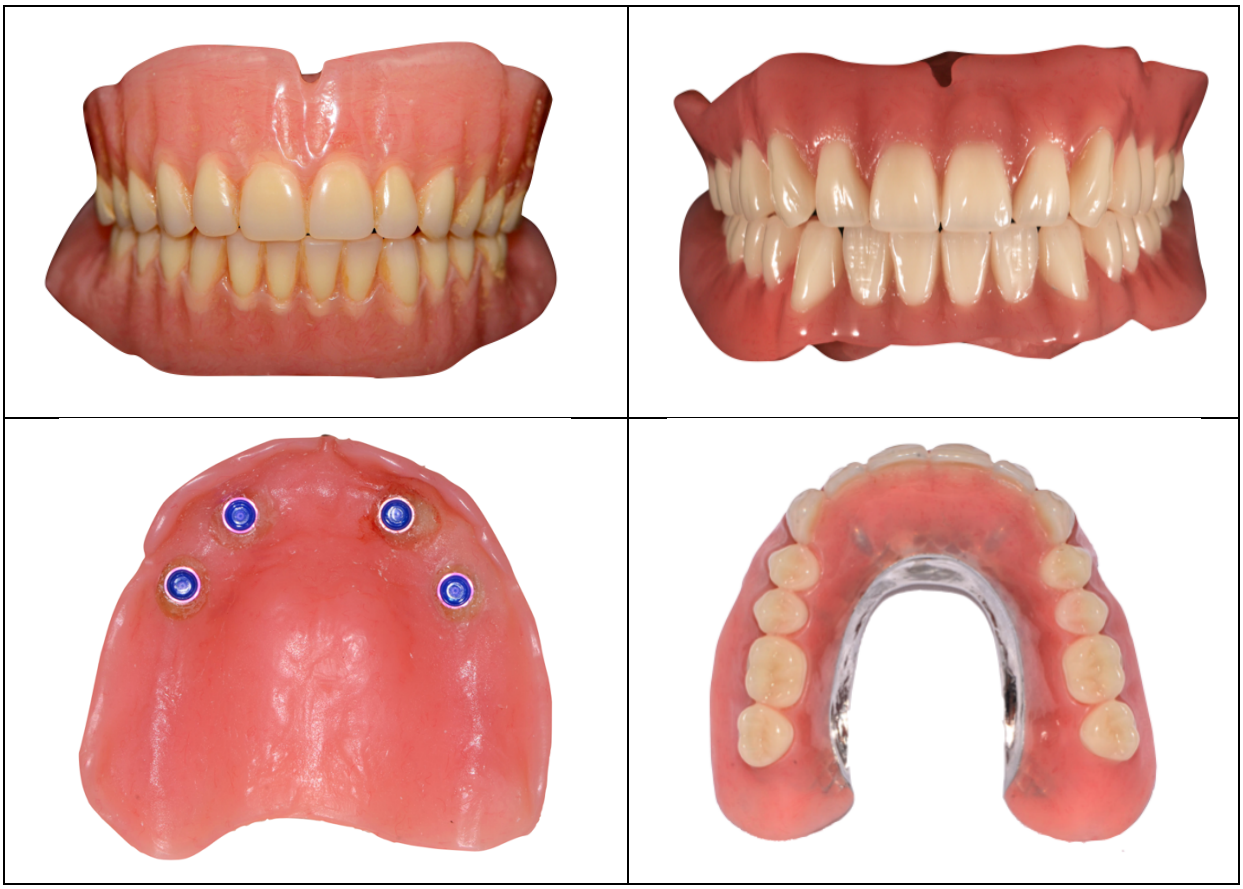


Figure 9: Prostheses 1-4

3. Prosthodontic Procedures

Initial maxillary and mandibular diagnostic alginate impressions were made. Custom impression trays were fabricated using initial diagnostic models between appointments. Final impressions were made using heavy body polyvinyl siloxane (PVS) for border molding and light body PVS wash (Aquasil Ultra, DENTSPLY Caulk, Milford, DE). Wax rims were fabricated on the poured final model using baseplate wax on a triad base. Bite registrations were obtained be taken using either PVS material or Aluwax (ALUWAX DENTAL PRODUCTS COMPANY, Allendale, MI). Facebow registration was taken to mount the maxillary final impression cast on Stratos 300 articulator. Various

molds of Dentsply TruExpression (DENTSPLY Prosthetics, Ontario, Canada) and Ivoclar Phonaris II (IVOCLAR VIVADENT, Schaan, Liechtenstein) denture teeth were used for selection by the clinician and patient. After selection these teeth were set in accordance with proper esthetics and lingualized balanced occlusion principles. Esthetic wax try-in appointment was performed and esthetics approved by the participant prior to final fabrication. Dentures were processed in acrylic using the Ivocap system (IVOCLAR VIVADENT, Schaan, Liechtenstein).

Denture insertion was completed using wax for adjustment of borders and pressure indicating paste for intaglio surface of dentures. Occlusion was evaluated using articulating paper. Comfort and esthetics was verified by the clinician and patient. Participants were given denture home care kit including strict instructions on cleaning denture as well as intra oral tissues. Participants were seen 1 week post insertion to evaluate for sore spots and confirm proper occlusion. Dentures were adjusted minimally where necessary. Participants had subsequent visits for denture adjustments as needed throughout the study as well as after completion of the study. Participants who required dental treatment in their mandibular arch were simultaneously treated in this arch as would be done customarily through the Graduate Prosthodontics clinic.

For fabrication of the final implant overdenture, after insertion of the locator abutments and housings (Zest Anchors LLC, Carslbad, CA) was completed, a clear resin duplicate of the existing conventional denture with space relieved for a wash impression served as the custom tray. The denture duplicate was used to make the final impression using coe-comfort soft reline material (GC American Inc, Alsip, IL), as well as to register the intermaxillary relation. A facebow or occlusal fox plane was used for

mounting the maxillary model (depending on clinician preference and use of articulator average mounting plates) and bite registration was obtained using this duplicate. A putty matrix was created on the denture impression of the clear duplicate tooth position prior to separating the models to allow for placement of the teeth in a similar arrangement to the first fabricated denture. After mounting and separation of the denture duplicate impression, the final impression was sent to the lab for fabrication of the palateless denture metal framework in Vitallium® alloy (DENTSPLY, Hasselt, Belgium) (TRIAD Dental Studio, Greensboro, North Carolina). Teeth set on the framework were tried in for esthetic and functional approval by the clinician and patient prior to processing. Final dentures were processed similar to the first dentures using the Ivocap system (Ivoclar Vivadent, Schaan, Liechtenstein).

4. Radiographic and Surgical Procedures

Participants presented to UNC Radiology Clinic for a dual scan protocol as described by Simplant for the fabrication of a mucosa-supported 3D Safeguide. Scanning acquisition was performed by a third year Radiology resident. The denture with 8 to 12 properly dispersed fiduciary markers (Suremark, The Suremark Company, Simi Valley, CA) was scanned using a CS 9300 CBCT scanner (Carestream, Rochester, NY). The field-of-view (FOV) was 10x10 cm in order to fully capture the denture and allow for segmentation in the Simplant software. The CS 9300 has a feather setting for a low dose protocol which allowed for the denture and denture markers to be captured. The imaging parameters for the 10x10cm FOV feather setting were 400 μm, 85 kVp, 4 mA, 3.7 seconds, 14.8 mAs, and dose area product (DAP) was

271 mGy/cm^2 (milligray per centimeter squared). The DICOM data was exported at the acquisition voxel size (400 μm) and uncompressed.

The patient was scanned wearing the dentures with attached fiduciary markers in the mouth and the upper and lower jaws were separated with either a radiolucent bite registration or gauze. The patient was scanned with a CS9300 with field-of-view (FOV) of 17x11 cm. The imaging protocol was 180 μm voxel size, 85 kVp, 6.3 mA, 10.3 seconds, 64.89 mAs, and the dose area product (DAP) was 1950 mGy/cm^2. The patient was positioned using a chin and forehead rest. After exposure, the volume was reviewed for quality control which consisted of any motion or air between the soft tissue and the denture were present as well as ensuring all of the denture and denture markers were captured. If the scan was determined inadequate, the patient was rescanned using the same protocol given approval of the patient. The DICOM data was exported at the acquisition voxel size (180 μm) and uncompressed. The patient scan was reviewed by a board certified oral and maxillofacial radiologist at the UNC School of Dentistry. Interpretation reports were uploaded into the patient's electronic patient record on a secure data base and then reviewed by the prosthodontist prior to implant planning and treatment.

Simplant 17.0 Software (SIMPLANT, DENTSPLY Implants NV, Hasselt, Belgium) was used for implant planning. The segmentation wizard was utilized to generate clear 3D models of anatomical structures of the patient's maxillary bone, sinus location and other anatomical structures. The patient scan was merged with the denture scan using the dual scan feature of the software. All fiduciary markers were evaluated on both the patient and denture scans to ensure accurate merging. Once merged, the dual scan

allowed visualization of the desired final tooth setup in the CBCT images and digital implant planning was performed using following objectives: i) adequate bone surrounding the implants in all directions for proper stabilization of the implant after placement, ii) adequate restorative space for the given soft tissue and final prosthesis components, iii) emergence angulations of the implants as parallel as possible given bone dimension to allow for appropriate insertion of the prosthesis and decrease off angle stress on the locator abutments.

Participants with sufficient bone allowing placement for proper placement of implants were allowed to continue in the study. Those without adequate bone who remained interested in implant placement for facilitation of this prosthesis were given their treatment options for sinus augmentation or grafting to be treated outside of the study. Participants were allowed to voluntarily end the study at any point given their satisfaction prior to moving forward with each new procedure and one patient chose not to have implants placed due to his satisfaction with a new conventional denture. 15 participants fulfilled appropriate requirements and were continued in the study for implant placement. The final surgical plan for placement of the four Dentsply Astratech OsseoSpeed EV implants (DENTSPLY Implants, Mölndal, Sweden) was approved by prosthodontic faculty and Simplant 3D Safeguide with sleeve and drill components were ordered. Upon receiving the surgical guide and placement protocol all components were verified as present and accurate prior to the surgery.

Surgical pre-op and post-op instructions were reviewed at the visit prior to surgery and each patient given the opportunity to ask remaining questions regarding the upcoming surgical visit. The day of surgery each patient completed a pre-operative oral

rinse for 1 minute with Peridex (chlorhexidine gluconate 0.12%). Pre-operative antibiotics of amoxicillin 500mg were given or 600mg clindamycin if the patient has allergy to amoxicillin.[67] Standard UNC Graduate Prosthodontics clinical protocol for implant placement was used including full body sterile drape of patient as well as surgical scrub of both operator and assistant. Local anesthesia was used at surgical site (2% xylocaine 1:100,000 Epinephrine), unless it was determined that the patient cannot have epinephrine and they were then given (3% Mepivicaine, no epinephrine).

Simplant guides were placed in patient's maxilla and fit verified using pressure indicating paste prior to application of local anesthesia. Once fit was verified, location of planned sites were marked onto tissue through the guide and the guide was then removed and patient given local anesthetic appropriately for these sites. Guided Anchor Pins (Nobel Biocare Services AG, Zürich-Flughafen, Switzerland) were inserted following verification of reseating the guide fully after anesthesia. A Flapless surgical technique was implemented whenever participants presented with adequate keratinized tissue around implant sites which included a tissue punch removal directly over sites for implant placement. For participants with thin buccal keratinized tissue, a full thickness flapped approach was implemented and the seating of the guide on lingual mucosa and opposing occlusion verified. Implants were placed according to Dentsply Osseospeed Safeguide protocol unique for each patient guide. Locator abutments or healing abutments were placed for participants who qualified for a flapless technique and if all 4 implants demonstrated ISQ measures of 70 or greater using the Osstell. When Osstell was not available for evaluation, torque values at time of implant placement of 45 Ncm was used to determine if coverscrew or healing abutment was placed. If implants

demonstrated ISQ values below 70, torque below 45 Ncm, or a flapped procedure was implemented, coverscrews were placed. For participants where flapped procedures were implemented, 3-0 chromic gut sutures will be placed for appropriate closure. Some participants required recontouring of hard and soft tissue around planned implant sites and therefore this was completed under copious irrigation to allow for proper seating of abutments.

Panoramic radiographs were taken after implant placement to verify location of placement. The participants' dentures were relieved in the sites where abutments were placed at the time of surgery. Participants were given appropriate verbal and written post-operative instructions as well as prescribed Peridex (chlorhexidine gluconate 0.12%) rinse to use twice daily for 2 weeks following the first day of surgery. Participants were also provided with a post operative prescription of Ibuprofen 600mg and/or hydrocodone to take as needed provided no allergies to these medications. Customary follow-up was completed 1 week after surgery to verify adequate and acceptable healing of surgical sites and denture comfort. Participants requiring second stage treatment had this completed at least 12 weeks post placement based on DENTSPLY EV Implant recommended guidelines. Participants had implant locators attached to their denture at the earliest of 12 weeks post implant placement.

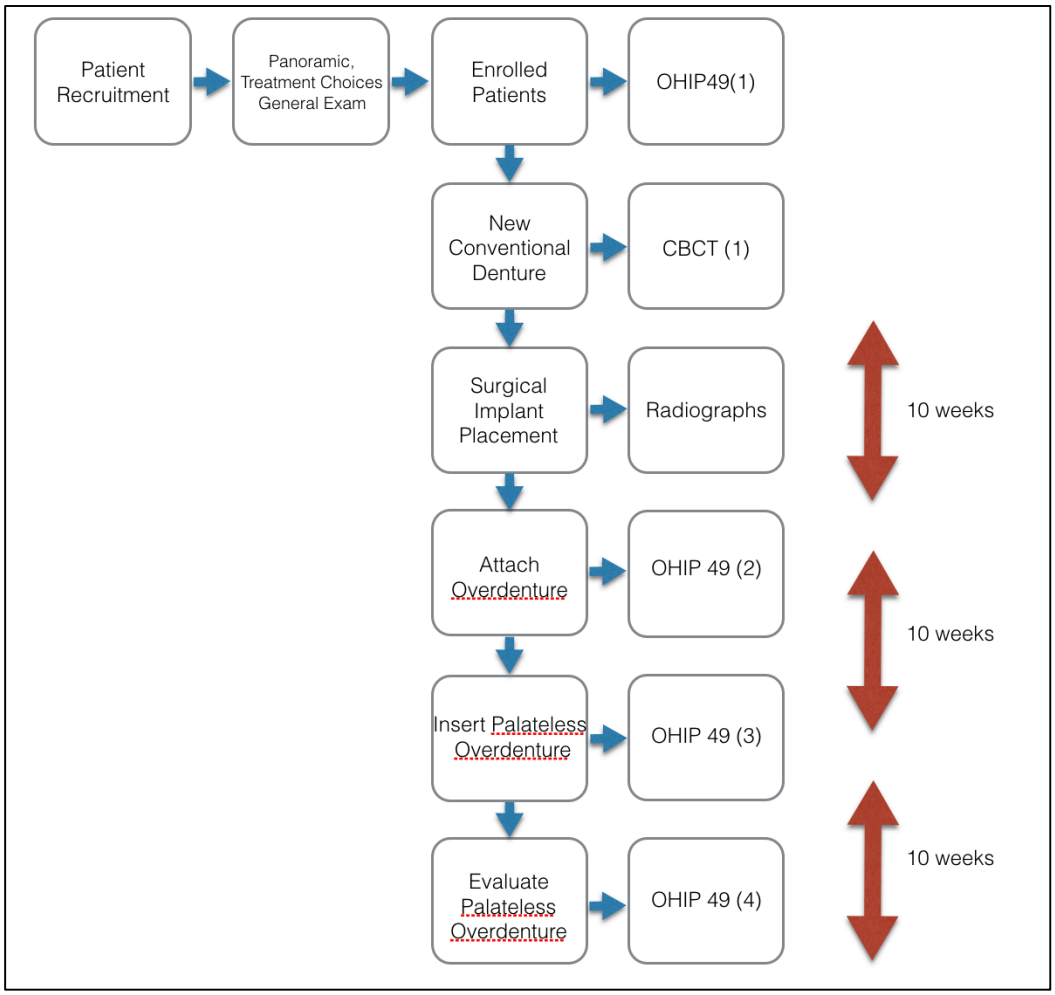


Figure 10:Oral Health Impact Profile (OHIP) Timeline

5. Patient Reported Outcomes and Statistical Methods

The OHIP 49 questionnaire was selected for the patient reported OHRQOL measures to evaluate participants based on seven domains of: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Prior to starting fabrication of the new conventional dentures, participants completed the first OHIP 49 questionnaire, which was a patient reported reflection of their existing prosthesis, termed baseline. Participants then completed the questionnaire again at least 2 months (approximately 10-12 weeks for

most participants) post insertion of each of the new prostheses: new conventional denture, implant retained full palate denture, and the final implant retained palateless denture (Figure 6).

At the time of reporting, all 19 participants who met initial inclusion and exclusion criteria provided completed questionnaires at baseline. At the time of CBCT evaluation to determine adequate amount of bone volume in the anterior maxilla for implant placement without grafting, 2 participants became disqualified for inclusion in the study due to lack of adequate bone volume. These participants were offered additional treatment options which included sinus augmentation and bone grafting for implant placement or to remain with their new conventional complete denture as their final restoration. Both participants chose to restore the edentulous maxilla with the conventional dentures and not proceed with additional treatments for implant placement. One patient chose not to proceed after changes in her financial condition precluded affording the treatment prior to surgery and another patient chose not to proceed after feeling such satisfaction after the new conventional denture was inserted that he did not desire additional treatment with implant placement. All patient questionnaires that were completed, regardless of whether they left the study early, were included in statistical evaluation. Amount of participants at each Prosthesis time-point is noted in Figure 6.

Of the 15 participants continuing with placement of implants and additional study procedures, 14 provided completed questionnaires for ‘new conventional denture’, 6 completed questionnaires for ‘implant retained overdenture’, and 3 completed questionnaires for ‘implant retained palateless overdenture’ as well as post treatment

questions. The OHIP-49 data as well as post treatment question data was input on an excel file by the investigator and verified by another person prior to statistical analysis.

OHIP asks about the frequency with which specific problems with teeth, mouth or dentures adversely impact quality of life. Responses are made on a five-point ordinal scale coded 0 (never or not applicable), 1 (hardly ever), 2 (occasionally) 3 (fairly often) or 4 (very often) and were evaluated as recommended by Slade.[58,60] Higher scores denote more frequent adverse impacts, and hence worse quality of life. The OHIP-49 severity score was the dependent variable, computed as the sum of all ordinal responses. Severity scores have a potential range of 0 to 196.[68] In analysis, any missing value for an OHIP item was replaced with the sample mean computed from non-missing responses to the relevant OHIP item. The seven OHIP-49 subscale scores were also computed to identify which dimensions of satisfaction were most and least responsive to treatment. A linear mixed model tested the statistical significance of change in OHIP- 49 severity score from the baseline scores at the three follow-up times: at 10 weeks post insertion of conventional denture; at 10 weeks post pickup of locators in interim denture termed as implant retained overdenture; and at 10 weeks post insertion of the final prosthesis, termed palateless implant retained overdenture. Values were also evaluated for significance between subsequent prostheses.

RESULTS

Table 3: Selected characteristics of study participants and mean (standard deviation) OHIP-49 severity scores at baseline (n=19)

	N	%	Mean (sd) baseline OHIP-49 severity score	
Total	19	100.0	71.2	(8.7)
Sex				
Male	9	47.4	67.9	(32.4)
Female	10	52.6	74.1	(44.0)
Age (y)				
<65	8	42.1	63.8	(29.4)
65–74	6	31.6	83.3	(50.7)
≥75	5	26.3	68.4	(37.9)
Race				
White	16	84.2	69.3	(38.1)
Non-white	3	15.8	81.0	(44.0)
Number of years edentulous				
<1	6	31.6	69.5	(40.3)
1 to 2	4	21.1	56.8	(33.6)
>2	9	47.4	78.7	(40.6)
Type of prosthesis at enrollment				
Immediate	6	31.6	76.3	(41.6)
Conventional	13	68.4	68.8	(37.8)
Status of opposing dentition				
Completely edentulous w/CD	2	10.5	86.5	(2.1)
Completely edentulous w/OD	5	26.3	95.2	(38.9)
Completely edentulous w/ISFD	2	10.5	22.5	(13.4)
PE w/oPRDP	1	5.3	59.0	(0.0)
PE w/PRDP	7	36.8	65.4	(39.9)
Tooth	2	10.5	70.5	(41.7)
Provider of pre-study prosthesis				
DDS student	5	26.3	85.2	(27.9)
General dentist	3	15.8	85.3	(31.5)
Prosthodontic resident	7	36.8	78.4	(44.8)
Prosthodontist	4	21.1	30.3	(8.6)

Participants treated included 9 men and 10 women aged from 49 to 88 years. The majority had been edentulous in the maxilla for at least one year. Variation was

evident in the types of opposing dentition as well as the training of clinicians who fabricated the baseline maxillary prosthesis (Table 4).

OHIP-49 severity scores obtained at baseline for 19 participants ranged from 13 to 142 (Prosthesis 1) (71.2, sd 8.7).

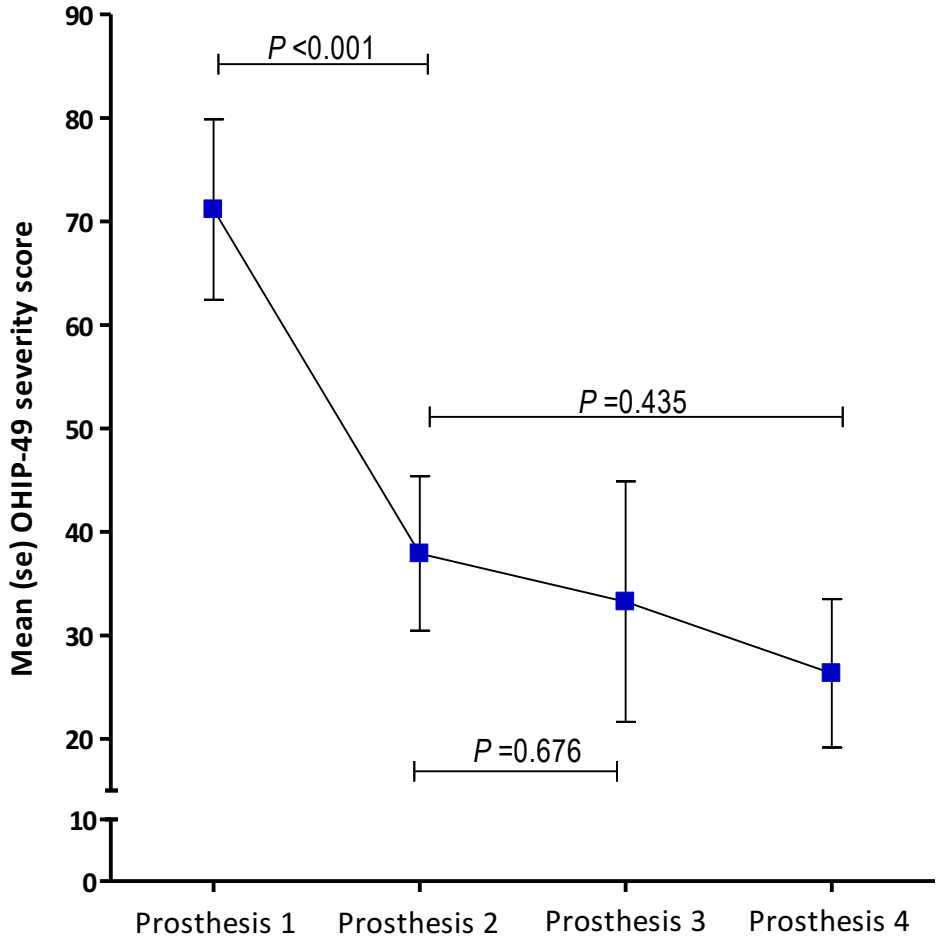


Figure 11: Mean (se) OHIP-49 severity scores at four treatment stages. Treatment was associated with a statistically significant reduction in mean OHIP-49 severity scores from baseline level, but scores at follow up of wear of subsequent prostheses of implant-retained overdenture and palateless implant-retained overdenture were not significantly lower than scores at follow-up of new conventional denture

Table 4: Difference in mean OHIP-49 severity scores at visits 2, 3 and 4 relative to baseline visit

	Beta coefficient	95% CI	P>z
Prosthesis 1	Ref		
Prosthesis 2	-33.2	-48.6, -17.9	<0.001
Prosthesis 3	-37.9	-59.4, -16.4	0.001
Prosthesis 4	-44.8	-73.6, -16.0	0.002
Intercept	71.2	56.9, 85.4	<0.001

Table 5: Mean (standard error) OHIP subscale score for each prosthesis, and change in OHIP subscale score following rehabilitation

	Functional limitation	Pain and discomfort	Psychological discomfort	Physical disability	Psychological disability	Social disability	Handicap
Prosthesis 1	17.8 (1.6)	11.8 (1.3)	8.9 (1.1)	16.1 (1.5)	6.9 (1.0)	3.5 (0.8)	6.2 (1.0)
Prosthesis 2	10.1 (1.8)	7.3 (1.4)	4.3 (1.2)	8.5 (1.7)	2.5 (1.1)	1.6 (0.9)	3.8 (1.1)
Prosthesis 3	11.1 (2.6)	5.7 (2.1)	2.8 (1.7)	7.8 (2.2)	2.6 (1.5)	1.3 (1.3)	1.4 (1.5)
Prosthesis 4	5.3 (3.6)	5. 9 (2.8)	4.9 (2.2)	5.5 (2.9)	1.6 (2.0)	0.2 (1.8)	2.3 (2.0)
Absolute difference [a]	12.5	5.9	4.0	10.6	5.3	3.3	3.8
Percent change [b]	70.5	50.2	44.6	65.8	76.6	95.6	62.2

[a] Computed as the mean subscale score for prosthesis 4 subtracted from the mean subscale score for prosthesis 1

[b] Relative difference in mean subscale score from prostheses 1 to 4, expressed as percent change

Because observations measured longitudinally are more highly correlated within patients than observations between patients, we fit linear mixed-effects models specifying fixed effects for mean OHIP severity scores and different random intercepts for each patient. In the null mixed model, the intraclass correlation coefficient was 0.347, meaning that 34.7% of the variance in OHIP severity scores was attributable to individual differences between patients, and not to treatment. Treatment was associated with a statistically significant reduction in mean OHIP-49 severity scores from Prosthesis 1 to Prosthesis 2 (P =<0.001), but scores recorded for Prosthesis 3 and Prosthesis 4 did not differ significantly from Prosthesis 2 scores (Figure 11).

Post insertion data for the new conventional denture (Prosthesis 2) compared to the baseline prosthesis (Prosthesis 1) were obtained for 14 of the 15 patients continuing in the study. For these patients, mean OHIP-49 scores reduced by 38 OHIP units, on average, from their baseline level of 71.2 (Table 4). Not only was this reduction statistically significant, but the magnitude of reduction exceeded the threshold of minimal important difference of 6 units[69] by a factor greater than six-fold.

The OHIP subscale analysis was completed and the 7 theoretical hierarchy of domains for the four prostheses were calculated (Table 5). The absolute and relative

differences in mean subscale scores achieved by rehabilitation (i.e. the difference between prostheses 1 and 4) was also calculated. Prosthesis 4 resulted in the greatest absolute reduction in functional limitation while the greatest relative reduction was seen for social disability. Dental problems that interfered with social interaction fell by a massive 96%.

At the time of reporting, OHIP-49 data from the post insertion of implant retained overdenture (Prosthesis 3) were obtained for 6 patients. Further small reductions in OHIP-49 scores compared to Prosthesis 1 were observed at this time. Among the 3 patients who completed all treatments and all 4 questionnaires, OHIP-49 severity scores continued to decrease compared to Prosthesis 3. Treatment was associated with a statistically significant reduction in mean OHIP-49 severity scores from Prosthesis 1, but scores at Prosthesis 3 and Prosthesis 4 were not significantly lower than Prosthesis 2 scores permitting rejection of the null hypothesis that patient reported outcomes would remain the same throughout various prostheses.

The 40 surviving implants used for both implant retained prostheses (Prosthesis 3 and 4) placed in 10 patients are currently functional without pain, infection, or mobility at this time. No prosthetic complications have been reported during the short follow-up.

DISCUSSION

All patients requesting implants for rehabilitation with implant-retained palateless overdentures presented with common conventional denture problems including poor retention, pain, problems with eating and speech, and poor esthetics. Baseline mean OHIP for the present study was 71 which is consistent with a study by Allen who found a range of 55 to 104.[23] When the OHIP was created by Slade and Spencer they found that functional limitation was the most frequent domain among edentulous patients (69%) while physical pain was the most prevalent domain for dentate (71%).[58] A clinical trial by Allen showed that baseline subscale scores for dentate patients were much lower for each of the seven OHIP domains compared to edentulous subjects. When further evaluating baseline values for the edentulous patients, he compared those patients requesting new conventional prostheses and those requesting implants for retention of their removable prosthesis. He concluded that "subjects who requested implants had the poorest oral health prior to treatment and edentulous subjects who received the treatment of their choice reported significant improvement in their oral health-related quality of life."[23] He also found that given improvement in OHIP in patients with new conventional dentures compared with pre- operative prostheses, those subjects who did not receive implants who requested them, were still relatively dissatisfied. He states "there are two possible reasons for this, namely: (a) these subjects did not receive their treatment of choice, and were therefore biased in their

opinion of conventional dentures, and (b) their complaints could not be rectified using conventional prosthodontic techniques, even when treatment was provided by a specialist."[23] It is well known that the acceptance of complete dentures is difficult to predict and not necessarily correlated with the condition of the residual anatomy or quality of the prostheses provided.[23,56] It has been recommended that adequate attempts be made for adaptation to a conventional prosthesis prior to recommending further improvements with implants.[57,61,70] As implant treatment becomes patients' preferred option, given the variation in adaptability to the edentulous condition, our ability as clinicians to satisfy patients through attempting a more conservative treatment with a new conventional prosthesis may continue to become more limited.

Baseline prostheses included in this study consisted of both immediate and conventional prostheses. It is argued that the transition from dentate to edentulism is in itself a significant experience in which more problems and dislike with the first prosthesis may be expected. Patient adaptation has been shown to be greatly varied among individuals however, further statistical evaluation will be performed to determine if the patients starting with an immediate prosthesis had differing baseline OHIP scores compared to those with a conventional initial prosthesis. By also evaluating the difference in OHIP unit change from conventional prosthesis to implant prosthesis, in relation to time of edentulism, this may result in trends showing that the longer one wears a conventional prosthesis, less improvements are found with the addition of implants. Regarding adaptation, a 2 month period was used between prostheses to allow enough adaptation for patient reported evaluation as recommended by previous

studies.[63] Other authors have suggested that this may not be enough time for older individuals as it is shown that they take longer to adapt to oral prostheses.[8,34]

Regarding baseline prostheses, a trend was present in this study of poorest outcomes with baseline prosthesis correlating to lowest training level of providing clinician. This suggests that the quality of the provided prosthesis, and subsequently adjustment and maintenance, does play a role in patient-reported outcomes of conventional removable prostheses. This was supported by studies which show that senior dental students and general dentists are less likely to identify errors related to base extension and occlusal vertical dimension compared to prosthodontists.[9,40] As the quantity of edentulous patients seeking treatment continues to increase, combined with the significant patient reported improvements apparent in fabrication of a new satisfactory conventional prosthesis, our findings further support the continued training of conventional removable prosthodontics in dental schools suggested by other authors.[2] A recent survey of general dentists in Iowa found that the majority of them are still making complete and partial removable dentures and that 68.1% had made at least one set of complete dentures in the last 3 months.

In the present study, comparison of mean OHIP scores between baseline prosthesis and new conventional prosthesis showed an average reduction of 38 OHIP, which was both statistically and clinically significant. This follows John and Steele's definition of the "minimal clinical difference" for the OHIP-49 of 6 units constituting a minimal clinical difference.[69] A further trend of continued decline in adverse oral impact was shown from the conventional prosthesis to the implant-supported palateless prosthesis, however no statistical significance was found between the implant-retained

denture or the palateless implant- retained denture compared to the new conventional denture. Similar findings were reported by Heydecke et al.,[71] Zembic and Wismeijer,[34] and substantiated in a systematic review by Sadowsky et al.[72] The review reported almost no improvement in general patient satisfaction, stability, retention, esthetics, mastication and speech for implant-supported maxillary dentures when patients were satisfied with their current maxillary conventional dentures.[72] This may have been what was represented after the fabrication of the new conventional denture. One patient chose to decline further treatments with implant placement due to his significant improvement in satisfaction from baseline to the new conventional prosthesis, however the remaining patients still chose to pursue implant placement.

Although the review by Sadowsky found that the addition of implants showed minimal clinical improvements based on patient reports, it does not necessarily correlate with findings of the present study as not all of the studies reviewed used the OHIP to measure patient-reported outcomes, nor did they evaluate the change in each outcome separately (patients in study were evaluated at the time of implant retention of prosthesis and then separately at removal of the palate). The lack of systematically evaluating patient-reported outcomes using standardized methods, such as the OHIP, has led to great variations seen in these outcomes across research in dentistry.

Similar to a study by Zembic, the implant- retained dentures used in this study did not change with respect to the appearance with the conventional dentures, thereby removing the variable of esthetics.[34] This allowed patients to evaluate a change from a suction retained conventional denture to one of implant retention, and then separately of removal of the palate. Similarly, for the fabrication of the final prosthesis, a duplication

technique was used in conjunction with the same tooth mold and shade as the previous prosthesis, which further controlled variables of esthetics and speech based on tooth position. Although at the present time not all patients have been evaluated, each sequential change in the evaluated prostheses did yield a 6 unit difference, suggesting that these changes may be viewed as clinically significant. Some studies argue that maxillary implant-supported prostheses should not be considered as a general treatment option for patients with good bone support or for patients satisfied with their conventional prostheses.[34,73] Although statistical significance may not be found for this small study population, the minimal clinical difference defined as 6 units suggests that based on this study, the use of implants to further improve patient outcomes, regardless of satisfaction with a new conventional prosthesis, may be warranted.

The minimal difference noted from patients wearing the new conventional denture (Prosthesis 2) to implant-retained denture (Prosthesis 3), could be due to the clear clinical difference in retention of a poorly fitting conventional prosthesis to one with good retention. This may mean that the benefits one might expect from retention using implants were not seen to be drastic due to the new conventional denture fitting so well. Patients have reported psychological benefits of retention with adhesives and implants regardless of clinically visible difference. Furthermore, differences observed between the two implant retained prostheses compared to the new conventional denture must be understood in the scale of overall improvement. With such a drastic change in OHIP to Prosthesis 2, there only allows so much more improvement for each additional change as there is no way based on the scale that each subsequent change can result in 38 unit change each. The ability to evaluate the effect of subsequent variables as in this

study design therefore becomes challenging to analyze in the scheme of understanding what variable in the treatment process makes the greatest impact for patients.

During the time of evaluation of Prosthesis 3, not only did the patients gain the benefits of retention of the implants, they also experienced the potential anxiety, pain, and discomfort during healing which coincides with the placement of dental implants. Slade described this as a potential complication in the evaluation of the OHIP, as bidirectional results may lead to a washout appearance of effect as the benefits and downfalls of the given experience are opposite.[60] Additionally, patients were also required to incorporate additional hygiene measures around the intraoral locator abutments as compared to the edentulous arch, as well as adapt to the insertion and removal of the prosthesis. Another limitation of this study was the inability for a cross-over component to evaluate the effects of implant placement and palate coverage. A particular strength in the study was the incorporation of digital technology in the realm of a dual scan radiographic technique, implant planning, surgical guide fabrication, and flapless surgical technique when applicable. This technology resulted in reduced time during surgery as well as appeared to result in improved patient comfort during implant placement as well as post operatively, which is supported by other reports.[74,75]

It is clear that additional patient reported outcomes are desired to aid in clinical decision making and public policy recommendations. In order to further define clinical significance, given such patient variability, clear and defined expectations and endpoints must be created by the clinician and patient prior to initiating any treatment for edentulism. As highlighted by the 2008 ITI consensus conference, there is a need for further clinical trials to validate treatment recommendations for implants supporting

overdentures[76] as it has been shown that less than 2% of studies on implant overdentures evaluates patient reported outcomes.[77]

The treatment of maxillary edentulism with implant overdentures provide a more cleansable, cost effective, and often simpler surgical solution as compared to fixed alternatives. Further studies of a greater sample of patients could aid in the development of more standard guidelines for implant placement similar to those which were necessary to determine the mandibular 2 implant overdenture as the standard of care treatment for the edentulous mandible throughout many countries.[12] Although the use of less implants has shown success in retention of a palateless overdenture,[34] 4 implants has been accepted as a more predictable treatment modality.[44] Further patient-centered studies of adequate size are required to develop public policy changes for maxillary edentulism in the future.

CONCLUSIONS

The placement of 4 implants for restoration with a palateless implant-retained overdenture appears to be a viable treatment option to improve patient reported oral health quality of life outcomes. Statistical significance was found between baseline prostheses and new conventional dentures only, suggesting that many patients may be satisfied simply with a new, technically well made, and esthetically pleasing conventional maxillary denture.

APPENDIX A: ORAL HEALTH IMPACT PROFILE QUESTIONS AND SUBSCALES ADOPTED IMAGE FROM FIGURE 1 [59]

Functional limitation

1. Have you had difficulty chewing any food because of problems with your teeth, mouth, or dentures?
2. Have you had trouble pronouncing any words because of problems with your teeth, mouth, or dentures?
3. Have you noticed a tooth which does not look right?
4. Have you felt that your appearance has been affected because of problems with your teeth, mouth, or dentures?
5. Have you felt that your breath has been stale because of problems with your teeth, mouth, or dentures?
6. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth, or dentures?
7. Have you had food catching in your teeth or dentures?
8. Have you felt that your digestion has worsened because of problems with your teeth, mouth, or dentures?
9. Have you felt that your dentures have not been fitting properly?

Physical pain

10. Have you had painful aching in your mouth?
11. Have you had a sore jaw?
12. Have you had headaches because of problems with your teeth, mouth, or dentures?
13. Have you had sensitive teeth, for example, due to hot or cold foods or drinks?
14. Have you had toothache?
15. Have you had painful gums?
16. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth, or dentures?
17. Have you had sore spots in your mouth?
18. Have you had uncomfortable dentures?

Psychologic discomfort

19. Have you been worried by dental problems?
20. Have you been self-conscious because of your teeth, mouth, or dentures?
21. Have dental problems made you miserable?
22. Have you felt uncomfortable about the appearance of your teeth, mouth, or dentures?
23. Have you felt tense because of problems with your teeth, mouth, or dentures?

Physical disability

24. Has your speech been unclear because of problems with of your teeth, mouth, or dentures?
25. Have people misunderstood some of your words because of problems with your teeth, mouth, or dentures?
26. Have you felt that there have been fewer flavors in your food because of problems with your teeth, mouth, or dentures?
27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth, or dentures?
28. Have you had to avoid eating some foods because of problems with your teeth, mouth, or dentures?
29. Has your diet been unsatisfied because of problems with your teeth, mouth, or dentures?
30. Have you been unable to eat with your dentures because of problems with them?
31. Have you avoided smiling because of problems with your teeth, mouth, or dentures?
32. Have you had to interrupt meals because of problems with your teeth, mouth, or dentures?

Psychologic disability

33. Has your sleep been interrupted because of problems with your teeth, mouth, or dentures?
34. Have you been upset because of problems with your teeth, mouth, or dentures?
35. Have you found it difficult to relax because of problems with your teeth, mouth, or dentures?
36. Have you felt depressed because of problems with your teeth, mouth, or dentures?
37. Has your concentration been affected because of problems with your teeth, mouth, or dentures?
38. Have you been a bit embarrassed because of problems with your teeth, mouth, or dentures?

Social disability

39. Have you avoided going out because of problems with your teeth, mouth, or dentures?
40. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth, or dentures?
41. Have you had trouble getting along with people because of problems with your teeth, mouth, or dentures?
42. Have you been a bit irritable with other people because of problems with your teeth, mouth, or dentures?
43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, or dentures?

Handicap

44. Have you felt that your general heath has worsened because of problems with your teeth, mouth, or dentures?
45. Have you suffered any financial loss because of problems with your teeth, mouth, or dentures?
46. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth, or dentures?
47. Have you felt that life is generally less satisfying because of problems with your teeth, mouth, or dentures?
48. Have you been totally unable to function because of problems with your teeth, mouth, or dentures?
49. Have you been unable to work to your full capacity because of problems with your teeth, mouth, or dentures?

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