THE IMPACT OF MANDIBULAR 4 MINI DENTAL IMPLANT SUPPORTED OVER-DENTURE ON PATIENT'S SATISFACTION AND QUALITY OF LIFE

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ABSTRACT

Objectives: Mini Dental Implants (MDIs) or ultra-small diameter implants have been developed and recognized as a viable method to retain mandibular overdentures. Although the clinical effectiveness of this intervention has been assessed in many studies, there is limited evidence regarding Patient Reported Outcomes (PROs) with this treatment. Therefore, the purpose of this study is to evaluate patients' ratings of their satisfaction and quality of life after receiving 4 MDI retained mandibular overdentures.

Methods: Eleven eligible edentate individuals (F=5, M=6; ages 54-84 years; mean =68.8) who responded to an advertisement for implant retention for dental prostheses in a local Montreal magazine were selected to participate in this quasi-experimental study (pre-post-intervention design). After signing an informed consent, each received 4 MDIs (3M ESPE) using a standardized non-invasive flapless protocol. Implants were loaded immediately after placement using the patients' original dentures. Participants were asked to complete the OHIP-20 questionnaire and rate their satisfaction on a 100 mm Visual Analogue Scale (VAS) instrument, consisting of nine different domains (ease of cleaning, general satisfaction, ability to speak, comfort, aesthetics, retention and stability, ability to chew, function and oral condition), at baseline and 6 months following implant placement.

Results: The OHRQoL scores demonstrated a moderate to large degree of improvement in of all the OHIP-20 domains (ES; 0.52-1.03). The largest change was found in the Handicap domain (ES=1.03) and the smallest change was in the Physical Pain domain (ES=0.52). Moreover,

differences in the mean change scores were statistically significant in all domains, as well as in the total OHRQoL score (Wilcoxon signed-rank test, $p<0.05$).

Compared to baseline, ratings were higher at 6 months (Wilcoxon signed-rank, $p<0.05$) for general satisfaction, ability to speak, stability, ability to chew, function and oral condition ($P<0.05$). However, there was no significant change in satisfaction recorded in the domains of ease of cleaning, comfort and aesthetics ($p>0.05$).

Conclusion: The mandibular 4 MDI over-denture appears to significantly improve patient-centered outcomes in edentate individuals and can be a satisfactory option for patients who would like improvement in their denture-wearing experience.

Keywords: Mini Dental Implant (MDI), Edentulism, Prosthodontics, Oral Rehabilitation, Patient-reported Outcomes (PROs), Oral Health Related Quality of Life (OHRQoL)

RÉSUMÉ

Objectifs: Les Mini-Implants Dentaires (MID) ou des implants d'ultra petit en diamètre ont été conçus et reconnus en tant que méthode viable pour la rétention de prothèses mandibulaires. Bien que l'efficacité clinique de cette intervention a été évaluée dans de nombreuses études, il existe des preuves limitées concernant les résultats rapportés par les patients avec ce traitement. Par conséquent, le but de cette étude est d'examiner les évaluations des patients par rapport à leur satisfaction et leur qualité de vie après avoir reçu 4 MID Prothèses fixées mandibulaires.

Méthodes: Onze individus éligibles édentés (F=5, H=6, âges 54-84, moyenne=68.8), qui ont répondus à des annonces dans des revues locales de Montréal pour implant fixé pour des prothèses dentaires, ont étés sélectionnés pour participer dans cette étude quasi expérimentale. Après la signature d'un formulaire de consentement, chaque participant a reçu 4 MIDs (3M ESPE) utilisant une méthode normalisée, non-invasive, sans volets. Les implants ont été chargés immédiatement après le placement, en utilisant les prothèses originales des patients. On a ensuite demandé aux participants de remplir le questionnaire RAMO-20 et d'évaluer leur satisfaction sur un instrument d'Echelle Visuelle Analogique (EVA) de 100 mm, composé de neuf domaines différents (facilité de nettoyage, satisfaction générale, la capacité de parler, le confort, l'esthétique, la rétention et la stabilité, la capacité de mastiquer, la fonction et la condition bucco-dentaire), au départ et 6 mois après la pose de l'implant.

Résultats: Les résultats pour le test de la qualité de vie relative à la santé bucco-dentaire (OHRQoL) démontrent un niveau modéré à importante d'amélioration pour chacun des domaines RAMO-20 (ES; 0,52 à 1,03). Le changement le plus important a été constaté dans le domaine

Handicap (ES = 1,03) et le plus petit changement a été noté dans le domaine de la Douleur Physique (ES = 0,52). En outre, les différences dans les résultats de changement moyennes étaient statistiquement significative dans tous les domaines, ainsi que dans le score total OHRQoL (le test Wilcoxon signed-rank, p <0,05).

Parallèlement, par rapport à la valeur initiale, l'indice de satisfaction était plus élevé à 6 mois (le test Wilcoxon, signed-rank p <0,05) pour: la satisfaction générale, la capacité de parler, la stabilité, la capacité de mastiquer, la fonction et la condition buccale (P <0,05). Cependant, on a constaté aucun changement notable quant à la satisfaction pour les domaines de: facilité de nettoyage, le confort et l'esthétique (p> 0,05).

Conclusion: Les prothèses mandibulaires complètes 4 MDI semblent améliorer de façon importante les résultats de santé axés sur les patients chez les personnes édentées et peuvent constituer une solution satisfaisante pour les patients qui souhaiteraient constater une amélioration par rapport à leur expérience de leur port de prothèse.

Mots-clés: Mini Implant Dentaire (MID), Édentement, Prothèse, la Réhabilitation Orale,

Résultats Rapportés par les patients (RRP), La qualité de vie relative à la santé bucco-dentaire (OHRQoL).

DEDICATION

To my dear parents, ***Jafar Vakili*** *and* ***Manijeh Zeinali;***

who supported me throughout my life and directed and taught me everything I needed to become a different person.

To my beloved husband, ***Dr. Mohammad Amir Samimi*****;**

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who showed me how strong they were during the last few years. Thank you for your patience and understanding and for being such considerate children. I am so proud of both of you. Maryam, you are my best friend, thank you so much for helping me and studying so hard. Abood, I hope you can follow your dream in playing in international soccer matches.

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CONTRIBUTION OF CANDIDATE & MANUSCRIPT CO-AUTHORSHIP

1- All the statistical analysis and data interpretation for the first six months of the study have been conducted by the candidate.

2- The candidate presented the findings of this longitudinal study on April 3rd 2015 at the Annual Research day of the Faculty of Dentistry, McGill University, Montreal, Canada.

3- In addition to writing different sections of the thesis, the candidate wrote the complete manuscript (Patient Reported Outcomes of Mandibular Mini-Dental Implant Supported Overdentures). However, the following co-authors contributed largely in different sections. Thanks to Prof. J. S. Feine and Dr. Shahrokh Esfandiari for the development of the protocol and the final revisions of the manuscript and thesis.

LIST OF TABLES

GLOSSARY OF ABBREVIATIONS

CD	Complete Denture
CER	Comparative Effectiveness Research
EBM	Evidenced-based Medicine
EMA	European Medicine Agency
FDA	Food and Drug Administration
HRQoL	Health Related Quality of Life
ICF	International Classification of Functioning Disability
ISOD	Implant Supported Over-denture
MDI	Mini Dental Implant
OHIP	Oral Health Impact Profile
OHRQ	Oral Health Related Quality of Life
OMIs	Orthodontic Mini-implants
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measures
VAS	Visual Analog Scale
WHO	World Health Organization

CHAPTER 1.0

INTRODUCTION

Edentulism is the complete loss of natural teeth (1-3), which meets the International Classification of Functioning Disability and Health of the World Health Organization (ICF/WHO) protocol definition of impairment disability and dysfunction, and is classified as physical handicap (4). This condition occurs mostly because of carries and periodontal disease and has a great impact on the oral and general health, as well as quality of life of the edentate individuals (2, 5-9).

Although edentulism has declined over the past 20 years, as a result of improved oral health, the disease still poses as a major issue worldwide (2, 10). In 2010, almost a quarter of the Canadian population (22%) between the ages of 60 to 79 years were completely edentulous. Furthermore, Canada, akin to other countries, is facing the issue of an increasingly large aging population. It is estimated that the senior population (people older than 65) will comprise 23.7% (10.4 million) of the total Canadian population by the year 2036. Therefore, during the next several decades, the number of elderly edentulous individuals who are in need of rehabilitation will increase (11).

Different treatment modalities have been introduced in order to reduce the disability and burden of this chronic condition. Although, for many years, maxillary and mandibular complete dentures have been counted as the best treatment for edentulous individuals, evaluating this conventional treatment has demonstrated a series of complications for the patients (7, 12).

Nonetheless, following the approval of the standard-diameter Dental Implant by FDA in 1976, this intervention has been applied increasingly in the world of dentistry as well as oral rehabilitation. There are numerous studies, which demonstrate the advantages of implant over-denture over the conventional complete denture and discuss its practical role in increasing the patient satisfaction and quality of life by advancing stability, retention and other psycho-social aspects (5, 7, 13-16). However, the anatomical considerations, like the lack of supporting structure and attached gingiva, the costs of device and operation (7, 17), the fear and anxiety of required surgical procedures, the long healing period and the postoperative complications (17, 18), are the most common barriers which have limited the patients' desire of this modality.

Mini Dental Implant (MDI) is a biocompatible titanium screw with the diameter of 1.8-2.4 mm, whose application in human jaw for prosthetic treatment has been approved by the Food and Drug Administration (FDA) (19, 20). Although its small diameter and high quality bone integration makes the device suitable to be applied in narrow alveolar ridges with insufficient bone mass (21), applying a non-traumatize and flapless placement procedure of MDI (22, 23) and its cost effectiveness (23, 24) have signified it as a credible alternative treatment for oral rehabilitation in edentulous patients. Additionally, MDI has the aptitude to provide immediate support for fixed prosthesis and over denture and, contrary to standard implants, no healing time is required after placement.

The quality and procedure of making the right choice, in particular circumstances, can be assessed by a variety of methods. Today, however, with great influence of patient-centred paradigm on the science of medicine and dentistry, the application of patient-reported outcome, in comparative effectiveness studies, has been increasingly developed. In addition, it is

noteworthy that reliable and appropriate instruments are the promising parts of the success chain in this regard.

Given the insufficient evidence on the implication of high quality PROM in evaluating the effectiveness of this state-of-the-art treatment modality in oral rehabilitation, the objective of his thesis is to assess the impact of the MDI implication of oral rehabilitation, with respect to the mandibular over-denture, on the quality of life and satisfaction of edentate patients.

CHAPTER 2.0

LITERATURE REVIEW

2.1 New Medicine Worldviews

Modern medicine, as Bensing has explained, is influenced by two different paradigms; 'evidence-based' and 'patient-centred' medicine (25). While, Evidence-Based Medicine (EBM) presents the most accurate treatment by the use of the best experimental studies and trials, empirical data and the best evidence (26, 27), increasing patient role and elevation of his/her experience and voice, by the aim of improving the quality of care, is emphasized in the Patient-Centered Medicine. This worldview promises that patient preferences are taken into account. Stewart has explained that the core of this paradigm is the need for integration of patient's view and physician best knowledge and expertise in order to achieve the most effective treatment (28).

The recent definition of EBM, however, has exponent integration of the patient value, empirical data of intervention and clinical expertise (26). Yet, Friesen-Storms et al (29) discussed that this part of modern medicine, has mostly concentrated on the clinical evidence. On the other hand, integration of these two paradigms via incorporating the patients' perspectives and preferences in EBM by measuring the Preference-Related Evidence and bringing more evidence in the patient-centred medicine has been highly recommended (25, 30).

2.2 Patient Reported Outcomes (PROs)

Patient Reported Outcomes (PROs) is an important aspect of patient-centred Medicine; measuring patients' health status from their own point of view in a standardized manner which can direct the clinical treatment by explaining the particular health goals (31). The US Food and Drug Administration (FDA) defines Patient-reported Outcome (PRO) as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (32).

As evaluation of the health related interventions is becoming more and more patient-centred (33), application of PRO has been dramatically increasing. It is emphasised that the patient's perspective, as a fact and consequence of what she/he experiences and cares about, should be considered in the decision-making processes.

2.2.1 Application of PRO

A) PRO in Comparative Effectiveness Research

PRO is an essential factor in Comparative Effectiveness Research (CER), by using patient collaboration and engagement, informs patient-centred medicine and decision makers of the best available health care options. In addition, CER addresses cons and pros of different health screening, diagnostic and treatment modalities in order to select and apply the most effective care and improve the health care delivery system (34). The Institute of Medicine (IOM) elucidates the comparative effectiveness as "the clinical and/or economic evaluations of specific medical interventions (including pharmaceuticals, medical devices and medical procedures)

germane to other available alternatives for a selected clinical indication" (35). Nonetheless, the integration of the patients' perception of their own health level with other biomedical outcome is the fundamental aspect of the patient-centred comparative effectiveness research (36).

In prostate cancer, for instance, the value of PRO in evaluating the effectiveness of different treatment modalities, was studied in a systematic review conducted by Efficace et al. (37). The study synthetized the data of 22,071 patients from 65 included RCTs with the PRO endpoint, between 2004 and 2012. The results indicated that 25% of these PRO RCTs provided sufficient evidence in selecting the treatment alternatives and revealed the critical role of PRO in assessment of treatment effectiveness.

Moreover, in many circumstances, biomedical outcomes will not provide sufficient evidence to find the effective treatment or health screening alternatives. Consequently, application of PRO is an available valid approach which evaluate the efficacy and effectiveness of the diagnostic, preventive or treatment interventions (38, 39).

Given the positive role of the patient-centred CER to inform decision makers, different organizations have been established to support this construct. For instance, the Patient-centred Outcomes Research Institute (PCORI) was established in the US with the goal of 'Patient Protection' and 'Affordable Care', providing funding for patient-centred comparative effectiveness research in March 2010 (40).

B) PRO in Label Claim

Today, patient experiences and their perspectives of care are an accepted outcome in health intervention approval procedures in the field of medicine. The European Medicine Agency (EMA), in 2005 (41) and the FDA, in 2006 and 2009 (32, 42), respectively, have published guidelines for using Patient-reported Outcomes (PRO) measures in the approval of pharmaceutical products and devices in medical product development to support labelling claims.

The level of PRO application in approved product labelling for new drugs was initially reported in a systematic review conducted by Willke et al. in 2004 (43). The study reviewed 215 product labels between 1997 to December 2002 in the US. The result indicated that PRO was reported in 64 (30%) of the total product labels, and the FDA approval of 23 products was based on PRO, as the only evaluated endpoint. Gnanasakthy et al. (44), also, published another systematic review in 2012 in which the product labels were assessed from January 2006 until December 2010. The study revealed that 28 (24%) of the total 116 reviewed products, reported PRO in which this outcome was granted as the primary endpoint for 20 (71%).

Likewise, Perrior et al. (45) in a recent paper, studied the products with PRO labelling claim that have been implied in treatment of the rare disease (i.e., neoplasms, endocrine diseases, nervous system diseases, pulmonary arterial hypertension, cryopyrin-associated periodic syndromes and severe pain) and obtained their and approval through EMA. To find the related products, however, on November 12, 2013, the EMA website and PRO Labels database (www.mapi-prolabels.org) were searched. They identified 69 ‘orphan medicine’ in the EMA website, out of

which 14 (20.3%) had a PRO claim. These PROs were focused on the Function; 2 product (14.29%), symptoms; 12 products (85.71%) and quality of life (QOL); 4 products (28.6%).

C) PRO in Clinical Care and Comparative Performance

The role of PRO in clinical care and comparative performance for health care delivery quality improvement is also remarkable. Clinical care aims to provide a situation of a better feeling for the patients (46); therefore, integrating PRO, along with patient's other clinical outcomes, can conceivably raise the quality of care.

In order to use Patient-reported Outcome (PRO) measures in clinical practice, the International Society for Quality of Life Research (ISOQOL) has developed a user's guide (47). A summarized report of the considerations of the guide has been published by Synder et al. (46). The report has mentioned several points pertinent to implementing patient-reported outcomes assessment in clinical practice, including:

1) identifying the goals for collecting PROs in clinical practice;
2) selecting the patients, setting, and timing of assessments;
3) determining which questionnaire/s to use;
4) choosing a mode for administering and scoring the questionnaire;
5) designing processes for reporting results;
6) identifying aids to facilitate score interpretation;
7) developing strategies for responding to issues identified by the questionnaires; and
8) evaluating the impact of the PRO intervention on the practice.

Moreover, the feasibility of using PRO in clinical practice and their comparative performance was assessed by Van Der Wees et al. (31) in a qualitative study in 2014. In this multi-centred study, 58 experts including 30 clinical practitioners, 11 measure developers and 17 leaders of performance measurement programs from 37 different organization in the United States, England, and the Netherlands were interviewed. The result revealed 3 main ways and purposes of PRO implementation; a) collecting PRO data in order to direct clinical care related to screening, diagnosis, treatment planning and treatment evaluation; b) collecting data by the state, regional or national organization to use in assessment of the organization performance; and c) a mixture of the first two methods. The participants also verified PRO as an important 'motivator' for health care quality improvement. Moreover, the result of the study indicated that PRO data collection and application in both clinical practice and performance measurement are feasible.

Similarly, in cancer care, the value and implication of PRO in improvement of patient outcomes was assessed in a systematic review conducted by Kotronoulas et al. (48). Twenty-six clinical trials were included; from which patient outcome (i.e. physical symptoms, quality of life, psychological symptoms and supportive care needs) were reported as the primary outcome in 21 articles (87.5%). Furthermore, process of care outcome (i.e. patient satisfaction, satisfaction with treatment/care/consultation; patient behaviours/actions) were discussed in 19 articles (79.2%).

2.2.2 Types of PRO

PRO is an ‘umbrella’ term, including different types of outcomes. Symptoms, functional status, health perceptions, and Health Related Quality of Life (HRQoL), in addition to other health related endpoints, like satisfaction, access to care, perceived treatment benefit or harm, health behaviours, comorbidities, treatment adherence and caregiver burden, are included outcomes under the PRO umbrella (36). Using the literature, the author also defines the outcomes:

> “… HRQoL; the extent to which one’s usual or expected physical, emotional, and social well-being is affected by a medical condition and/or treatment ... Health promotion Satisfaction with care: Patient satisfaction with care received.”

Health Related Quality of Life (HRQoL)

In 1993, Guyatt et al. (49) explained that quality of life, like terms, health status and functional status, indicates ‘health’. The authors also stated that: “[w]e use the term health-related quality of life (HRQL) because widely valued aspects of life exist that are not generally considered as "health," including income, freedom, and quality of the environment”.

Later, in 1995, WHOQOL group (50) defined the quality of life as “individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their personal goals, expectations, standards and concerns”.

Moreover, Cella (51) described the HRQoL as “the extent to which one’s usual or expected physical, emotional, and social well-being is affected by a medical condition and/or treatment”, and it is important to consider the multi-dimensional nature of health. Different models tried to show these dimensions and their correlations with each other.

In 1995, Wilson and Clearly (52) proposed a conceptual model of HRQoL in which biological, social and psychological components and their relations with one another and the quality of life had been conceptualized. The model consists of five different 'levels', namely biological and physiological factors, symptoms, functioning, general health perceptions, and overall quality of life, which are explained separately by the authors. The International Classification of Functioning (ICF) is another example which presents a classification of health and health-related domains. ICF is WHO's framework for measuring health and disability and has been approved since 2001 (53).

2.2.3 Patient Reported Outcome Measures (PROMs)

PROs are calibrated by Patient Reported Outcome Measures. Collecting accurate PRO data and achieving the purpose of the study is essentially based on the development or selection of a high quality instrument/measure.

Accordingly, along with considering single-item or multi-item questionnaires, it should be determined if the study objective can be fulfilled by use of a questionnaire that is 'tailored' to specific disease/population characteristics (disease-specific) or whether it is related to an outcome in a vast spectrum of healthy or diseased populations (generic) (36, 54).

Another classification of PROMs is whether they are health profile, preference-based or utility measures. While the former category assess a variety of health outcomes, the latter is based on the patients' preferences and other important factors (36).

Identifying an Appropriate PRO Measure

Since achievement of the PRO study objective is correlated with the selection of a valid and reliable measure, selecting a measure with high quality psychometric properties is challenging. To identify the available guidelines and the minimum standards connected with selecting PRO measures, Reeve et al. (55), in 2012, conducted a literature review followed by a survey. The study was carried out on behalf of the International Society for Quality of Life Research (ISOQOL) and was performed through MEDLINE, PsycINFO, and Combined Index to Nursing and Allied Health Literature (CINAHL) databases.

The review detected 387 related articles, which were based on ISOQOL drafted potential standards of PRO measures. Consequently, the draft was reviewed by the ISOQOL members, and minimum standards in PRO measures, qualified to use in CER and patient-centred medicine, were finalized in the form of final recommendations for documenting evidence in these six important areas: (1) conceptual and measurement model; (2) reliability; (3) validity; (4) interpretability of scores; (5) translation; and (6) patient and investigator burden.

A theoretical framework, or conceptual model, determines the relationship of domains and the outcomes in PRO measures. It also explains the measure approach and corporation of different dimensions, which are selected based on the study purpose and context, with the PRO outcomes (36).

Therefore, selection of a measure, with the established framework, will increase its accuracy in the evaluation of domains of interest and will simplify its interpretation. Furthermore,

considering the recommended key points will lead to the selection of an appropriate and applicable measure, which rises the quality and accuracy of the study.

2.2.4 PRO in Dentistry

Since 1990, patient-based assessments of oral health endpoints and application of Patient Reported Outcomes in the field of dentistry and the area of dental research, have dramatically increased (56). Consequently, the number of measures, to facilitate appropriate data collection procedure have been developed and tested.

The extensive implication of PRO to assess the efficacy and effectiveness of treatment in different major dental clinical research studies is also noticeable. In head and neck cancer, for instance, Bhalla et al. (57) have evaluated the effect of chemotherapy and radiotherapy treatment on the different aspects of patients life by measuring OHRQoL outcome through the use of the OHIP 14 measure.

Similarly, in 2014, the role of QoL in third molar extraction decision-making for patients with mild pericoronitis was evaluated in a clinical trial by Tang et al. (58). Furthermore, in fixed orthodontic treatment, significant improvement of the QoL score, as well as social and emotional well-being, has been demonstrated by Abreu et al. (59).

In periodontal and implant surgical procedures, patient's perceptions concerning pain, bleeding, swelling and bruising during the first week after surgery, were measured in an observational study conducted in Singapore National Dental Centre, in the period of 2009-2011. This study revealed that during the first week following different kinds of periodontal and implant installation surgery, PROs are "well tolerated". Moreover, the negative influence of the surgical

procedure duration and the application of periosteal releasing incisions on PROM was demonstrated in this study.

2.2.4.1 PRO in Prosthodontics

The evaluated outcomes of different trials in removable prosthodontics were systematically assessed by De Souza et al. (60), and the results were published in 2013. Ovid MEDLINE, for the period of 1985 to August 2011, was searched and 86 RCTs of removable prosthodontics in the six implant and prosthodontics journals were identified. In 43% of included articles, PROs were reported as the primary outcome of interest. While patient satisfaction was assessed as the primary outcome in 21 articles and as the secondary outcome in 4 articles, the quality of life-related outcome was reported in four papers (5%) as the primary and as the secondary outcome in two articles (2%).

Furthermore, in implant research, the role and frequency of PROs application in dentate and edentate population have been highlighted in two systematic reviews. In order to identify RCTs with the patient satisfaction and/or the quality of life outcome for evaluating mandibular retained over-denture, Emami et al. (61) conducted a systematic search in MEDLINE from 1966, EMBASE from 1980, the Cochrane Central Register of Controlled Trials and the Cochrane Systematic Reviews Database until 2007. They found 10 publications from seven different trials, in which the patients rated QoL and satisfaction in order to facilitate evaluation of implant supported over-denture effectiveness.

Furthermore, in 2012, McGrath et al. (62) published the results of their systematic review with the aim of presenting the application of PROMs in implant related research between dentate

population. This study conducted a structural literature search using the MEDLINE database, and the search strategy was adapted from the previous review. From 128 potentially effective articles, and after full text reviewing, 31 articles (including 25 RCTs) were confirmed for inclusion in the study. Twenty-two (71%) of the articles reported patient satisfaction and the other nine were primarily interested in the other health related outcomes such as pain, comfort and physical and social impacts of oral health.

As the result of these systematic reviews, the high level of evidence demonstrates that PROs have a significant role in the evaluation of different treatment modalities of oral rehabilitation. Although, patient satisfaction and OHRQOL are the most measured PROs in dental implant and prosthodontic studies, assessment of patient satisfaction represents the largest body of evidence.

2.2.4.2 Patient Satisfaction in Oral Rehabilitation

Patient satisfaction is one of the most important objectives of oral rehabilitation (63). Despite the variety of treatment modalities for oral rehabilitation, achieving patient expectations and providing satisfaction with the prosthesis is challenging.

The relationship between the different parameters, such as a patient's personality (64-66), age, gender, level of education (63, 67), previous denture experience (68, 69), patient's expectation (63, 70, 71), clinical quality of the denture (72-74) and satisfaction, have been investigated by different researchers. Not surprisingly, different studies reported different levels of effects of these parameters on patient satisfaction.

Although, considering the important factors for the patients can affect the success in achieving patient satisfaction (75), Feine et al. (76) has stated that "patient satisfaction with therapy is

likely to be the distinguishing outcome of many treatments for chronic diseases for which living with treatment is a more realistic objective than cure". Nonetheless, the evaluation of patient's assessment of their complete denture by Santos et al. in 2015 (63) declared that in conventional oral rehabilitation patient satisfaction exceeds their expectation, and this change is significant in the aspects of chewing and esthetics ($P<0.001$). In this study, 99 edentulous patients rated their pre-treatment expectation and post-treatment satisfaction, in the four aspects of aesthetics, chewing, comfort and phonetic on a Visual Analog Scale. Regression analysis of these data also revealed a positive correlation between the patient's expectation and his/her satisfaction in the aspects of esthetics and phonetics.

Similarly, significant improvement of patient satisfaction after receiving implant supported/retained over dentures has been reported in many studies (15, 77-79). To access these data systematically, Emami et al. (61) conducted a systematic review and meta-analysis of the available trials in which implant supported over-denture efficacy were assessed from the patients' point of view. Results of this review revealed that mandibular implant supported over-denture appears to be more satisfying for the edentulous patients than the conventional complete denture.

Furthermore, in an international multi-central trial study, in 2011, Rashid et al. (16) reported a significant greater improvement of patient satisfaction in the dimensions of general satisfaction, ability to chew and speak, comfort and stability ($p<0.05$) for the edentate individuals who received two implant supported mandibular over-denture in compare to conventional treatment. Data in this study, however, were collected from 102 individuals; 52 patients selected complete denture treatment and 49 patients selected implant supported overdentures at baseline and six

months after treatment from eight different international locations. Although both groups showed significant improvement of satisfaction in all aspects, except for the domains of ease of cleaning and ability to speak in the CD group. Significantly greater satisfaction in the four previously mentioned domains was reported only for the group of patients who were treated with implant supported over-dentures.

2.2.4.3 Measuring Patient Satisfaction in Oral Rehabilitation

Considering the increasing utilization and importance of this outcome in evaluating prosthodontic treatments among edentulous patients, it is essential to realize the satisfaction measurement and its influencing parameters. In 1969, a very simple questionnaire was used by Bolender et al. (80) in a study to evaluate the relationship between emotional problem and denture problem. The questionnaire consisted of 7 short questions related to appearance, retention, ability to chew food, ability to taste food, speech, comfort and patient expectation of their denture. Except the last question, the questionnaire was recording patients' responses in three-point scale of good, fair and poor.

In order to access the most precise results in denture evaluation studies, the use of a detailed, reliable and validated questionnaire was emphasized (81). To achieve these facts, however, in 1988, Vervoorn et al. (81) published a study in which the reliability and validity of a developed 'complaint questionnaire' for measuring patient's denture satisfaction was assessed.

Besides the 40 denture complaints, the developed instrument was evaluating the patient satisfaction in different aspects of general satisfaction, maxillary denture and mandibular denture satisfaction, appearance, retention and functional comfort.

Questionnaire was rated by two group of patients; group 1, with 113 completely edentulous patients waiting for receiving the treatment and group 2, with 102 patients who received the full denture 2-5 years ago. Conducting factor analysis, patient's denture complaints were classified in five different scales of functional complaints; maxillary and mandibular denture, vague denture complaint and two aesthetic related scales.

In assessment of the correlation between these scales and patient satisfaction variables, the authors demonstrated a high correlation between mandibular satisfaction and its functional complaints (r=0.79), consisting of patients view of lower denture loosening during eating, speaking and hurting in the time of eating food with different consistency.

Feine et al. (79) in 1994, also used a five dimensional Visual Analog Scale (VAS) questionnaire asking of retention, ease of cleaning, aesthetics, speech and function, in order to evaluate patient's considerations in choosing fixed or removable implant supported prosthesis. While patients rated denture stability and chowing ability as the most important factor in selecting of fixed-prosthesis, the aspect of ease of cleaning was the most influencing factor for choosing removable denture by the patients.

Concurrently, in order to measure patient's denture satisfaction, Feine and Awad developed a questionnaire (75), which results of its properties evaluation were published in 1998 (82). Item selection for this instrument, however, was based on three different approaches. Prosthodontists' opinion, items used in other studies and a qualitative interview with the patients in which patients were asked for the most important and influencing aspects of their denture.

Instrument was assessing the patient's satisfaction in the six different dimensions, including overall satisfaction, level of comfort, ability to chew, stability, ability to speak and ease of

cleaning of prostheses. Moreover, patient's responses were recorded in a 100 mm Visual Analog Scale (VAS) which higher rating was indicating greater satisfaction.

120 edentulous patients rated their level of satisfaction by the use of this instrument. 'Comfort' and 'ability of chew' were reported as the first and second most important factors of the denture, which affected the overall satisfaction by the patients (30%, 28.3%).

Furthermore, besides a significant and positive effect of all the dimensions on general satisfaction of patients, data analysis also revealed that all the aspects are significant predictors of the general satisfaction variable. Moreover, the aspect of 'ability to chew' was determined as the most effective factor on the patient's general satisfaction by multivariate regression analysis in this study.

The fact that, prosthesis functional characteristic, notably retention and chewing efficacy, is a positive influencing factor on patient's satisfaction, not only has been demonstrated from the patient point of view. Alfadda et al. (74) showed that clinically retentive mandibular denture is the most influencing clinical variable, affecting patient's satisfaction.

2.2.4.4 Oral Health Related Quality of Life (OHRQoL)

In dentistry, also, like medicine insufficient 'biomedical' outcomes and clinical model of oral health assessment has been highlighted by researchers (73, 83, 84), and the importance of considering the influencing aspects of life on evaluating of health has been mentioned.

Utilising the socio-dental indicators in the evaluation efficacy and effectiveness of oral health care system based on 'need to know' as Cohn (56) has mentioned was from the very first steps in

this journey. The need of a valid measure of socio-dental indicators or oral health outcome was also brought to attention by him.

Locker and Allen has defined OHRQOL as "the impact of oral disorders on aspects of everyday life that are important to patients and persons, with those impacts being of sufficient magnitude, whether in terms of severity, frequency or duration, to affect an individual's perception of their life overall".

This construct has been conceptualized based on the WHO classification of impairment, disability and handicap (85) by Locker in 1988 (86). In this model, psych-social and physical disability has been considered as a result of oral disease and its impairments.

2.2.4.5 Measuring of OHRQoL in Prosthodontics

In 2007, Locker and Allen (87) published an article, in which the increased number of available OHRQoL measures has been shown, as before the 1997 the article reported ten measures and more than six different measures after this year. The authors have mentioned seven criteria as the important points in evaluating the OHRQoL measure. Accordingly, it is important to consider the explicitness of the aim, construct and domains that are being measured, source of the items, level of importance of the measuring aspects to the target population and validity of measure.

2.2.4.6 Oral Health Impact Profile (OHIP)

Oral Health Impact Profile (OHIP) is one of the used instrument in measuring OHRQoL. This tool aims to measure the social impact of the oral disorders by calibrating dysfunction, discomfort and disability that are associated with that.

Measure includes forty nine items, which selected from a total of 535 statements, obtained from interviewing 64 dental patients aged 60 years or older in study conducted by Slade and Spencer (88). Items were placed in seven conceptual subscales, based on Locker's model (86), functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. In this measure, participant's' ratings were recorded on a five point Likert scale, 4 = 'very often', 3 = 'fairly often', 2 = 'occasionally', 1 = 'hardly ever' and 0 = 'never'. The instrument was evaluated in 122 patients and a high internal and external reliability (Cronbach's alpha, 0.70-0.83 in six subscales) and (interclass correlation coefficient, 0.42-0.77) has been reported for this measure (88).

Examining the measure in a 1217 dental patients aged 60 years or older, Slade (89) derived a short form (OHIP 14) of this tool by eliminating: a) the items related to the denture wearers; b) the items which were kept unanswered or marked as 'don't know' by 5% or more respondents; and c) using statistical analysis, internal reliability, factor analysis and regression, for the remaining items.

Considering the excluding of denture related items and its potential of 'floor effect' after using this new version of the measure in edentate patients, Allen and Locker (90) conducted a study to develop a short version of OHIP, which can be used for edentulous patients and prosthodontics. The item reduction in this study was based on item impact method. Study conducted in two different centres, in Ontario, Canada with 121 participants and Newcastle, UK with 57 patients. Patients were asked to fill few numbers of the health status measures and item impact score was calculated for each study centre. Accordingly, the percentage of respondent for each item of OHIP-49, and its related mean score was calculated. To obtain the frequency of each impact,

however, the percentage of respondent to that impact was multiplied by its mean score. Then, this result was multiplied by the weight of each related item. The first two item with the highest impact score were selected for each subscale in the Canadian and British centre and OHIP-EDENT was shaped from their combination.

Calculating data by the three OHIP measures from the two different groups of patients, 22 patients who requested and received the implant supported over-denture and 35 patients, who received conventional denture in the UK centre, revealed that all measures have a high discriminative properties (Mann-Whitney test). However, calculating small effect size indicated a poor responsiveness for OHIP-14, OHIP-EDENT showed a good ability to measure change score.

2.3 Mini Dental Implant (MDI)

Mini Dental Implant or MDI is outlined as "implant fabricated of the same biocompatible materials as other implants but of smaller dimensions. Implants can be made as one piece to include an abutment designed for support and/or retention of a provisional or definitive prosthesis" (21). Yet, there is scarce confirmation around discriminant measures of Small/Narrow-diameter implants and Mini-dental implants that leads to interchangeable use of these terms. While 1.8-3 mm diameter implants have been considered as 'small-diameter implants' by Sohrabi et al.(17), implants with the diameter less than 3.5 are defined as narrow-diameter (91) and the one with diameter of 1.8-2.4 (24, 92, 93) or 2.7-3.2 (94) were classified as 'mini-dental implants'.

However, in a recent systematic review, Bidra et al. (21) discriminated the two modalities according to different factors such as; diameter, function, surgical placement procedure and cost. The authors classified MDI as the implants that are commonly designed as one piece with the diameter of 1.8-2.9 mm with ability of immediate loading. The small-diameter implants have a dimension of equal or greater than 3 mm and 2-piece design in this discrimination. Accordingly, small-diameter implants can be loaded immediately in addition to its ability of late loading and in opposite to the MDI which indicated as temporary implants in the beginning, its definitive application in fix prostheses has been reported.

With regards to number of implants needed for prosthetic rehabilitation in edentulous ridges, the review indicated an application of more than 2 MDI and considering the bone quality/quantity and economic as the governing factors in determination of small-diameter implants number. Additionally, economic consideration and cost were another considering factor in differentiation of these two types of implant.

2.3.1 Applications

A. MDI in Orthodontics

Dental Implants have presented a new paradigm in preserving Anchorage for orthodontic treatments. The MDI special qualifications, however, like the small size, lower cost, non-invasive surgical placement procedure, attracted a lots of attentions in this regard (95).

In a systematic review conducted by Reynders et al. (96) more than 80% success rate has been reported for application of this intervention in orthodontics. Moreover, based on available

studies, influencing factors on success rate have been divided in six different categories including, implant, patient, location, surgery, orthodontic, and implant-maintenance factors.

Furthermore in 2012, Papageorgiou et al. (97) published the result of their systematic review on the mini implants failure in orthodontic anchorage application. Searching nineteen electronic databases and reviewing the references of the including articles up to February 2011, fifty two RCTs were included in this study. Results of this meta-analysis revealed 13.5% failure rate for the 4987 miniscrew implants. A significant relation between the failure rate and the jaw and treatment duration ($p<0.05$) also was indicated in this study. Considering the available evidence in efficacy of MDI in orthodontics, in one of the latest related article Cousley and Sandler (98) stated that "OMI anchorage is at least as effective as conventional techniques, and it is preferred by patients to the alternative approaches available".

B. MDI in Prosthodontics

B.1 Transitional Implants

Mini Dental Implant has primarily presented in the field of prosthodontics as a temporary and interim treatment, providing function and aesthetic and stabilizing provisional restoration for edentate patients, who received permanent implant supported fixed/partial prostheses throughout their healing periods (19, 92).

In primary Branemark et al. two stage implant placement protocol (99) there is a need for three to six months load free healing period to induce osseointegration and obtain implant stability before the second stage of prosthesis placement. Accordingly, patients will stay tooth-less during

this time and experience some inconvenience conditions due to the influence of this transient situation on their chewing function, aesthetics and diet (92, 100, 101). To address these problems, Victor I. Sendax introduced the concept of mini dental implants and developed the very first design of this device before more than two decades (102, 103) to support fixed prostheses. Later on, the design has been modified and a one piece ‘o ball’ attachment has been added to the primary shape of MDI by R.A. Bulard (104).

Pertaining to this concept, many studies evaluated the usefulness of MDI as provisional treatment, in 2011 de Almedia et al (105) published a review on transitional implants to look at their characteristics, uses and behaviours during the definitive implant healing period. This review includes fourteen articles in this regard and indicated that the transitional implants’ diameter in the included articles varies from 1.8 to 2.8 mm with 7-14 mm different length, which were placed in distance of 1.5-2.5 mm from the final implants. It also demonstrated that besides the simple surgical and prosthetic procedures, transitional implants will provide retention and stability for denture, preserves edentates’ mastication, aesthetics, and speech and develop patients’ comfort during the definitive implant healing period.

Additionally, Ahn et al. (92) conducted a study in which 27 mini dental implants with the length of 13-18 mm and diameter of 1.8-2 mm were loaded immediately in the completely edentulous mandible of 11 patients. During the surgical procedure a 2 mm distance between each provisional MDI and final implant site was considered and patients’ old dentures were adapted to receive the metal housing by using a self-curing resins. As a result, during the average 21 weeks implication as provisional abutment for over-denture, 26 placed MDIs were remained completely stable and all the patients were satisfied due to their proper chewing function and appearance in

the healing period. Furthermore, it was observed that Osseointegration in the final implants was not affected by MDI.

B.1.1 Success Rate

Bone density and quality of bone is one of the most important factors in maintaining high success rate for transitional implants (92, 105, 106). Nevertheless, de Almedia et al. (105) reported a success rate more than 95% for transitional implants in their review.

El Attar et al.(101) also, conducted a clinical study to compare implant mobility and soft tissue healing in patients receiving immediate loaded transitional mini implant over-denture and patients with conventional complete denture. The comparison accomplished during the definitive implants healing period in twelve completely edentulous patients (F=6, M=6). Study results showed that 100% success (no mobility) of the transitional implants during the first and second months after their application and 83.3% success in the third and fourth post-delivery month. Moreover, less mucosal inflammation was reported in the patients who received immediate loaded transitional mini implant over-denture.

Concerning the transitional implant utilization in the fixed prostheses and partially edentulous patients also, Krennmair et al.(107) conducted a clinical study and analysed the data of 31 patients (F =18, M =13) who recruited to receive permanent implants and fixed partial prostheses. Patients were divided to two groups; group A (initial simultaneous) including 18 patients who received the definitive and provisional implants simultaneously, and group B (staggered procedure) including 13 patients who received implants following two different stages. Provisional fixed partial dentures were temporary cemented on the transitional implants

and natural prepared teeth for the duration of 3-9 months, until delivery of the definitive restorations. While 82.2% of provisional implants were being placed in the maxilla for a longer period of time (6-9 months versus 3 months for mandible), mandibular provisional implants demonstrated a higher stability. Accordingly, it was indicated that in the interval of the study and from the total of 98 provisional implants, only three transitional implants (3%) from the group B were failed and were removed before the definitive implants loading. All lost transitional implants were placed in the maxillary posterior region where did not have adequate high quality bone. Nonetheless, the authors concluded that meeting the patient comfort and satisfaction during the definitive implant healing period or augmentation procedure, transitional implants can be considered as a successful treatment modality.

Considering the importance of quality of bone in preserving success of transitional implants, a higher success rate in the mandibular transitional implants application versus maxillaries besides the need for less removal torque in the upper jaw comparing to the lower jaw, has been reported in different studies (92, 105-108).

Krennmair et al. (106) exhibited the difference of mandibular and maxillary transitional implants survival in a study of 28 edentulous patients. In this study, patients received 2-4 transitional implants in edentulous jaw, utilising denture support until the definitive implant loading stage (6-9 months versus 3 months in mandible). The result demonstrated a significantly higher loss of transitional implant in maxilla (36.2%. vs. 10.5% in mandible). Furthermore, it was observed that, maxillary implant loss was mostly occurred during the first four initial months. The authors also stated the difference in the bone quality between maxilla and mandible, as the reason of disparate success rate of transitional implants in the upper and lower jaws.

B.1.2 Histological and Osseointegration Behaviour

Stability of dental implants inside the alveolar bone is achieved and maintained by a direct connection between the bone and implant fixture, called 'Osseointegration'. Adell et al. (109) introduced this concept and explained it as: "firm, direct and lasting connection between vital bone and screw-shaped titanium implants of defined finish and geometry – fixtures". The authors also stated that obtaining this important feature depends on accuracy of the surgical procedure, duration of healing time and dispersion of the functional forces.

Development of Osseointegration in transitional implants was assessed by many researchers in animal and human bone tissue. This characteristic has been evaluated in de Almedia et al. (105) review also, and the authors clearly stated the developing of Osseointegration in the transitional implants.

Zubery et al.(110) examined the feature histologically in dog mandibular bone. Three Titanium implants with the diameter of 1.8mm and the length of 21mm were placed in the lower jaw of three dogs. Two of the three implants in each jaw were loaded by acrylic provisional restorations. Histological specimens were provided after 11-12 weeks of implantation through dissection of the jaw. The study illustrated that seven implants of the total twelve loaded implants were osseointegrated (53.8%), while this amount in the control group (unloaded implants) were three out of six (50%). In addition, a solid mature bone and a good contact with the implants were observed in the most osseointegrated implants.

In human population, however, histological evaluation of transitional implants, was conducted in a clinical study by Froum et al.(111). 33 Dentatus, pure titanium, transitional implants were

placed in 21 edentulous patients (17 implants in mandible and 16 in maxilla) and were used as abutment for acrylic resin provisional restorations in a period of 6-27 months. All the implants were intact and in function until the loading of definitive restoration, and no premature removal was reported during the study interval. Before delivery of definitive restorations, all transitional implants were removed by a trephine drills and the removed hard tissue submitted to the laboratory for histological evaluation. The study exhibited an average of 52.9% ± 13.81% Bone-to-Implant Contact (BIC) for transitional implants. Comparing to maxilla, a grater BIC in the mandible was observed (54.61% ± 12.74% in mandible and 51.09% ± 15.07% in maxilla). Based on the clinical and histological behavior and bone integration of transition implants in this study, the authors suggested a long-term research to assess the functionality of this modality alone or along with definitive implants for permanent restoration.

In 2012, Grassi et al. (112) reported the result of a case study that was conducted by the aim of a better evaluation of bone and transitional implant connection. The study used three dimensional (3D) procedure and Microcomputed tomography scanning (micro-CT) technology, providing higher-resolution 3D images of the bone tissue. In this case report, three transitional implants (3.00 mm in diameter) were placed in the completely edentulous mandible of a healthy, female 63 year old patient. While two of the transitional implants were immediately loaded by the patient's old denture for a period of three months, the other implant was remained unloaded as a control. Although progressive bone loss and failure in one of the implants was reported, the study found 73.19% BIC and a thick cortical bone in contact with implant collar.

B.2 Definitive Implants

High success rate, high quality/quantity of integration and Bone-to-Implant contact of mini dental implant whilst its implication as transitional treatment in prosthodontics (102, 105, 107, 113), proposed a new paradigm for its definitive application (111).

B.2.1 Clinical Performance

Results of different studies in this regard have been collected in a systematic review by Bidra et al. (21) in 2013. The review aimed to evaluate MDI survival rate, while used as definitive prosthodontic treatment modality in different durations of short term (1-5 years), medium term (5-10 years) and long term (more than 10 years) after surgery.

Although the search period was expanded from January 1974 to April 2012, there were only one randomized controlled trial, two prospective and six retrospective related articles included in this review, from two different databases. In the most included articles, MDI was implicated in the mandible to support the over-denture. The review revealed a first year Interval Survival Rate (ISR) of 94.7%, however. It also indicated that almost all implant failures were reported within the first year after the implant placement in all 9 studies.

Furthermore, the authors highlighted the limited evidence of assessment the effectiveness and survival rate of mini dental implants as definitive prosthodontics treatment with a medium-term follow up and they did not find any related article with a long-term and more than ten years follow-up.

In addition, clinical outcomes of mini-implants supported over-denture were assessed and published in a prospective observational study conducted by Preoteasa et al.(93) in 2014. The study used IMTEC/3M ESPE implants in available length of 10mm, 13mm, 15mm and 18mm and diameter of 1.8-2.1mm and 2.4mm in 24 patients with the mean age of 62 years.

In total, 110 implants were placed (36 in maxilla and 74 in mandible). Maxillary over-dentures were supported by 5-6 implants while patients were received 4-5 implants in the lower jaw to support their mandibular denture.

MDI status, over-denture status and patient overview were assessed to measure Success of MDI supported over-denture as the main clinical outcome in the study. Moreover, MDI status was evaluated by calibrating pre-implant marginal bone loss, availability of apical radiolucency and self-reporting pre-implant bleeding and implant mobility.

Patients were followed for a period of three years in the intervals of; weekly in the first month, 3, 6 months and 1, 2 and 3 year after the surgery. Study indicated a survival rate of 92.7%. There were 8 failed implants reported in the study, that all were placed in the maxilla and 86 implants were reported as successful treatment according to clinical criteria contains no mobility or sensitivity in functioning and detection of not more than two thread marginal bone loss .

In regards to over-denture status, 4 fractures in the lower and 2 fractures in the upper over-dentures were reported. Also, 5 dentures were relined during the three years period of the study.

Furthermore, five patients were complained from pain under the over-denture, while 20 patients reported continuous wearing of their dentures. Besides the survival rate and mobility of the implant, there are other clinical outcomes such as periodontal depth, gingival and periodontal

indexes that were evaluated in different studies in order to indicate success of this treatment modality.

Elsyad et al. (24), in 2011, published an article in which radiographic and periodontal findings of MDI supported over-denture, in addition to survival rate endpoint, were assessed in a three year follow-up prospective study. Twenty eight healthy edentulous patients within the range of 49-75 years, were received four sandblasted acid-etched, “O” ball head MDIs with the diameter of 1.8 mm and length of 12-18 mm. Concurrently, patients’ denture were modified and placed in accurate occlusal function.

Intra-oral radiographs were collected using the long-cone paralleling technique and were processed by the use of an automatic machine. Moreover, Plaque index, pocket depth (PD), gingival index and Periotest Value (PTV) were recorded as clinical endpoints to evaluate the MDI status. Both the radiographic and periodontal measurements were assessed in the intervals of 6 months, 1, 2 and 3 years after the implant placement surgery.

Result of this prospective study indicated the significant increasing of the horizontal and vertical marginal bone loss within the first year of implant application while, there were no significant differences in bone resorption observed within the one, two and three year interval examinations. Furthermore, the same statistical pattern was reported in regard to clinical and periodontal indexes.

Few years later, Scepanovic et al.(114) evaluated the clinical performance of MDI through measuring stability and pre-implant marginal bone resorption. In this prospective cohort study, 30 completely edentulous patients received 120 MDI with the diameter of 1.8mm and the length of 13 mm in the lower jaw. Study assessed the MDI primary stability by the use of Periotest

Classic devise and immediately after MDI placement, while secondary stability was measured during 3th and 6th weeks, 4th, 6th and 12th months follow up sessions with the same method. Concurrently, intra oral radiographs were used to measure implant marginal bone resorption. Study indicated the high MDI primary stability. However, an increasing of PTV and reduction of stability between the 6th weeks and 6th months after MDI placement was illustrated. Moreover, pre-implant marginal bone resorption did not show significant change after one year of MDI function and was measured as -0.4 mm.

B.2.2 Advantages of Definitive Implants

B.2.2.1 Inadequate Bone Structure Implication

Although Implant supported over-denture (ISOD) has introduced as the "first choice standard of care'' in edentulous patients (7, 115), when the quantity or quality of the available bone is not meeting the requirement for implant placement, its application will be challenging(21, 24). While there are few pre-prosthetic surgical treatment namely; residual ridge augmentation, bone graft and vestibuloplasty (21, 116) that will be proceeded for the patients looking for implant treatment with inadequate alveolar bone structure, compromised health condition in elder population not always allows their application.

However, MDI has proposed a new horizon in this regard. Therefor the primary indication of MDI in oral rehabilitation is in narrow and flat ridges (104). Recently, Garhnayak et al. (117) reported successful application, increased satisfaction and chewing ability after placement MDI in order to support mandibular over-denture in a 60 year old female patient whose inadequate mandibular bone structure does not allow standard implant implication. Patient received 4 MDIs with the diameter of 1.8mm and length of 10 and 13 mm in the anterior portion of mandible. The patient's exciting lower denture was adjusted and O ring housings were place in the inner side of the denture.

In partially edentulous ridges with insufficient bone mass, also, Balaji et al.(113) showed the efficacy of MDI in rehabilitation and prosthodontic treatment. This retrospective study indicated a 90.9% success for 2.4mm diameter MDI used as single restoration abutment in the patients with inadequate alveolar bone and minimum 5mm alveolar ridge width or inter-dental space.

Few years before this report, D. Singh et al. (104) in 2011 and Tadic et al.(116) in 2012, also reported successful application of MDI in patients with knife-edge and resorbed mandibular alveolar bone.

B.2.2.2 Economic Benefits

Implant retained / supported prostheses have a high initial expenses which can limit its application in elder edentate individuals in general and low income edentulous population in particular. Economic considerations of dental implants has been evaluated in a systematic review published by Vogel et al. (118) in 2013. The review assessed cost and cost-effectiveness of implant supported prostheses in compare to conventional fixed and removable prosthodontic treatments through searching three databases between the year of 2000 and 2010. Results of this review illustrated that comparing to conventional fixed partial restorations, implant supported prostheses is a cost-effective treatment modality for single missing tooth replacement. In regards to complete or partially edentulous ridges, however, the review indicated implant supported dentures as a high costly treatment besides its great effectiveness, patients' satisfaction and quality of life.

High costly implant technology also assessed with other treatment choices. In 2014 Schwendicke et al. (119) published an article in which cost-effectiveness of implant supported prosthetic treatment in molars with furcation involvement was compared with other alternatives. Study used an adopted tooth-level Markov model and performed Monte-Carlo simulation of a 50-year-old patient in 6-month cycles for molar with degree I, II and III furcation involvement. Result indicated that Scaling and root planning is the most cost-effective modality in molar with degree

I furcation involvement, while implant supported crown was the most expensive treatment. Moreover, retaining the periodontal involved tooth.

On the other hand, comparing to standard or small diameter implants, MDI has been introduced as a less costly technology by researchers like Griffitts et al. (23) and Bidra et al. (21). Simple and easy MDI placement technique, also, is another factor influencing the lower cost of MDI. As of the treatment cost in 2005, Griffitts et al. (23) presented that the cost of 4 MDI is equal to one standard implant.

B.2.2.3 Simplified Surgical Procedure

In addition to the effect of edentate's medical condition on the implant success rate (120-123), this factor is one of the preliminary keys to indicate or contraindicate implant placement surgical procedure. Although, Gómez-de Diego et al. **(**121**)** ,in a systematic review in 2014, designated that cardiac disease, controlled diabetes and metabolic disorders are not a complete contraindication for dental implant placement, yet there are many medical conditions that can limit or contraindicate the surgical implication to implant placement(120, 124-126). As, recent myocardial infarction or cerebrovascular accident (<6 months), recent valvular prosthesis placement or transplant (<6-12 months), High risk of bleeding (INR >3-3.5, platelet count <50,000/mm3), Significant immunosuppression (total white count <1,500-3,000 cells/mm3), Active cancer therapy, Intravenous bisphosphonate treatment and some psychological conditions have been considered as an 'absolute' surgical procedure contraindication for dental implant placement(125, 126), initiating of surgical procedure in these situations could be life-threatening. Furthermore, psychological impact of implant placemen surgical methods is another factor which

can affect patient's desire to select this treatment modality. S.Ellis et al. (18) in a qualitative study demonstrated that fear of experiencing pain due to implant placement surgical procedure and post- surgery complications are the main reason of not accepting implant treatment in edentate patients who are even dissatisfied from their conventional complete denture.

There are very limited evidence in regards to patient's medical condition consideration in MDI placement method. However, its simplified surgical procedure and flapless technique heightened it as a recommended lower risk procedure in oral rehabilitation for medically compromised patients. Bidra et al. (21) reported its less post-surgical discomfort and patient's morbidity in their systematic review.

B.2.2.4 Immediate Loading

MDI has shown its competency in immediate loading protocol, histologically and clinically (21, 24, 92, 94, 110, 114, 127). This qualification of MDI, primarily, granted edentulous patients with function, aesthetics and satisfaction in the functionless implant placement healing period.

However, along with shifting MDI implication paradigm from transitional to definitive indication of this technology, possibility of immediately loaded restoration and mastication for patients and reducing treatment time was an important advantage in MDI utilization. As from the patient's perception, a satisfaction rate of 94.4% and significant improvement in OHLQoL has been reported in edentulous patients receiving implant supported over denture following immediate implant loading protocol (100).in standard implant, Although, the evidence in long term application of immediate loaded prostheses over MDI is scarce, nonetheless, short and

medium term successful rehabilitation and increased patient's satisfaction has been reported (21, 93, 128).

In Implantology, Primary stability or 'the biometric stability immediately after implant insertion' is the basic factor for implant success (129, 130). Furthermore, the significance role of this important element and successful immediate loading of dental implant has been indicated in a review conducted by Fawad Javed et al. In 2010 (130). This review also, introduced implant design, bone density and surgical technique will influence the degree of acquired primary stability. There are different methods for measuring primary stability in dental implants, namely; Periotest, Resonance frequency analysis and cutting torque resistance analysis, reliability, sensitivity and specificity of these methods has been used evaluated in different studies(131-136).

Considering the importance of primary stability in the degree of successful immediate loading implants protocol, it is also essential to evaluate this factor in MDI placement. Scepanovic et al.(114) reported a PTV (periotest value) of -0.27 ± 3.41 as the primary stability and the mean PTV of 6 weeks post-surgical MDI placement equal to 7.61 ± 7.05, as secondary stability. Moreover, a range of PTVs from -3.6 ± 1.1 to -4.2 ± 1.2 for cumulative success rate of 92.9% were reported in a 3-year prospective study on mini dental implants supporting mandibular over denture by Elsyad et al. (24).

Although there is no confirmed threshold for this index, for standard implants, the amount of -4 to +2 has been used as the limit for a successful immediate loaded and osseointegrated implants , in many studies(137).

2.3.2 Patient-reported Outcomes

Using patient reported outcomes, efficacy and effectiveness of MDI has been assessed by very few researchers. Level of patient satisfaction following four MDI mandibular supported over-denture was quantified in a study conducted by Griffitts et al. (23). Data collected from 24 patients aged from 50-90 years old. Patients were asked to rate their satisfaction in the four different aspects of comfort, retention, chewing and speaking ability of the questionnaire, pre and five months post treatment. The greatest improvement was reported in the aspect of retention and comfort with the difference of 7.9 and 7.2 respectively followed by chewing ability with the reported difference of 7.0.

This endpoint also has been evaluated in a trial conducted by Preoteasa et al. (128).

Form the 36 edentulous patients recruited in the study, 18 patients were treated with the conventional complete denture and the other half received a 4 IMTEC MDI supported mandibular over-denture.

Results of the study revealed that, comparing to the first group (CD), the patients who were received the 4 MDI over-denture reported higher satisfaction in chewing ability and retention aspects. Concurrently, Tomasi et al. (138) evaluated patient satisfaction after MDI mandibular supported over denture in edentulous patients in a prospective study. 21 completely edentulous patients with poor stability and function of lower denture were selected for the study. After confirming the need and willingness of the patients to receive this treatment modality, each patient were received four Dentatus Atlas MDI in the mandibular anterior region and denture was being loaded. Using 10 centimetre Visual analogue Scale, patients rated their satisfaction at

three points of time, baseline, one month and 12 months after treatment. While, there was no significant change in satisfaction was reported between the one month and 12 months post treatment sessions, study illustrated a high level of improvement in patient satisfaction with respect to function and comfort after receiving four MDI retained over-denture

Furthermore, In 2012 Scepanovec et al. (127) published an article in which satisfaction and OHRQoL of the patients receiving MDI mandibular over-denture were evaluated for a period of one year. Thirty completely edentulous patient aged 65 years old or less and class I skeletal relationship with no osteoporotic, autoimmune and psychological disease recruited for the study. Primarily, all the patients received a complete denture. 15 weeks later, however, patients received 4 'O ball" 3M ESPE MDI in the mandibular interforaminal area. Lower denture was modified replaced for the patients within 24 hours post implant insertion session.

OHIP-EDENT and patient denture satisfaction questionnaire were rated by patients in two different sessions, 15 weeks after receiving each CD and MDI supported over-denture treatment.

Besides of 100% prosthesis success rate after a one year period of time, a significant improvement ($p<0.001$) in all domains of OHIP-EDENT and patient satisfaction endpoints except for maintenance of hygiene ($P= 0.603$) and aesthetic ($P= 0.451$) has been demonstrated in this study.

CHAPTER 3.0
RESEARCH MANUSCRIPT

Patients-Reported Outcomes of Mandibular Mini-Dental Implant Supported Overdentures

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Abstract

Mini Dental Implants (MDIs) or ultra-small diameter implants have been developed and recognized as a viable method to retain mandibular overdentures. Although the clinical effectiveness of this intervention has been assessed in many studies, there is limited evidence regarding Patient Reported Outcomes (PROs) with this treatment. Therefore, the purpose of this study is to evaluate patients' ratings of their satisfaction and quality of life after receiving 4 MDI retained mandibular overdentures.

Eleven eligible edentate individuals (F=5, M=6; ages 54-84 years; mean =68.8) who responded to an advertisement for implant retention for dental prostheses in a local Montreal magazine were selected to participate in this quasi-experimental study (pre-post-intervention design). After signing an informed consent, each received 4 MDIs (3M ESPE) using a standardized non-invasive flapless protocol. Implants were loaded immediately after placement using the patients'

original dentures. Participants were asked to complete the OHIP-20 questionnaire and rate their satisfaction on a 100 mm Visual Analogue Scale (VAS) instrument, consisting of nine different domains (ease of cleaning, general satisfaction, ability to speak, comfort, aesthetics, retention and stability, ability to chew, function and oral condition), at baseline and 6 months following implant placement.

The OHRQoL scores demonstrated a moderate to large degree of improvement in of all the OHIP-20 domains (ES; 0.52-1.03). The largest change was found in the Handicap domain (ES=1.03) and the smallest change was in the Physical Pain domain (ES=0.52). Moreover, differences in the mean change scores were statistically significant in all domains, as well as in the total OHRQoL score (Wilcoxon signed-rank test, $p<0.05$).

Concurrently, from baseline, satisfaction ratings were higher at 6 months (Wilcoxon signed-rank, $p<0.05$) for general satisfaction, ability to speak, stability, ability to chew, function and oral condition ($P<0.05$). However, there was no significant change in satisfaction recorded in the domains of ease of cleaning, comfort and aesthetics ($p>0.05$).

The mandibular 4 MDI over-denture appears to significantly improve patient-centered outcomes in edentate individuals and can be a satisfactory option for patients who would like improvement in their denture-wearing experience.

Introduction

Edentulism is the complete loss of natural teeth (1-3), which influences oral and general health, as well as the quality of life, of edentate individuals (2, 5-9). Although, as a result of improved oral health, complete tooth loss has declined over the past two decades, the disease is still a

major issue worldwide (2, 10), and the proportion of people who are in need of oral rehabilitation is increasing in developing countries (10, 11). However, different state-of-the-art modalities have played a significant role in minimizing the disability and dysfunction of edentulism (5, 7, 13, 139). Yet, the available evidence is lacking to determine which modality is most suitable in a given situation.

It has been largely believed that conventional biomedical outcomes, e.g. survival and disease-free survival, and clinically-based assessments of different treatment modalities are insufficient (140-143) when used as the only decision-making criteria. For instance, due to the prolonged survival period in early-stage prostate cancer, survival cannot be a valid endpoint for comparing different treatments (144). Additionally, the variety of clinical endpoints used in empirical studies and clinical trials is another drawback, making comparisons between different treatments more challenging (145).

To address these concerns, Patient-Reported Outcomes (PROs) have been increasingly used in experimental studies to assess the effectiveness of interventions and treatments (5, 8, 36, 146). It is widely perceived that patients' reports are valid reflections of their experiences (147) and can provide solid evidence of the effectiveness of the intervention from the patients' viewpoint (36, 55). PRO encompass various outcomes, including symptoms, functional status, health perceptions and Health Related Quality of Life (HRQoL).

Patient satisfaction and HRQoL are essential patient-reported outcomes (8, 36) that have been utilized in several studies in order to determine the quality of a treatment from the patients' perspective (142) and facilitate the comparison of different modalities (16). Ware et al.

explained that patient satisfaction measures two different elements; the care/component and the patient/determinant (142, 148).

Meanwhile, quality of measurement is a main factor in the accuracy and efficiency of these outcomes. Reaching a valid comparative conclusion by means of satisfaction evaluations or assessment of HRQoL depends mainly on the application of reliable and valid measures that enable us to observe treatment differences (36).

Patient satisfaction and quality of life have predominantly been used to assess different treatment modalities in the field of dentistry, in general, and in prosthodontics, in particular. A growing interest in research for the application of PROs in the assessment of implants and prosthetic treatment among dentate patients is demonstrated in a review by McGrath C et al. (62). Moreover, it was highlighted that patient satisfaction in these studies has been the most implemented endpoint. Patient satisfaction outcomes were assessed in 71% of included papers in this review, i.e. 22 out of a total of 31 papers. Similarly, in edentulous and partly edentate patients, the consistent use of this outcome has been exhibited in reviews conducted by Emami et al (61) and de Souza et al. (60) .

Several studies have evaluated the effectiveness of the conventional complete denture and implant retained over-denture using patient satisfaction measures. In middle-aged edentulous patients, Awad et al. (149) demonstrated that general satisfaction is significantly higher for patients receiving implant retained over-dentures than for those wearing conventional denture. Furthermore, in a multicentre study, Rashid et al. (16) showed that the edentulous patients who had selected implant retained over-dentures were significantly more satisfied than those who chose conventional dentures.

The Mini Dental Implant (MDI), or reduced diameter implant (1.8-2.4 mm), is a biocompatible titanium screw and one of the latest modalities in oral rehabilitation. The MDI's small diameter and effective integration into bone makes the device suitable for use in narrow alveolar ridges with insufficient bone mass (21). Applying a cost effective non-traumatic and flapless placement procedure (22-24) has made MDIs a potential alternative treatment for oral rehabilitation in edentulous patients. Moreover, MDIs have the ability to provide immediate support for fixed prostheses and over dentures.

While there are a number of studies in which the clinical effectiveness of MDIs has been evaluated (21), there is very limited evidence of patients' perceptions and the impact of MDI retention on different aspects of the lives of edentate individuals. Therefore, the objective of this study is the evaluation of OHRQoL in patients receiving 4-MDI overdentures.

MATERIALS AND METHODS

Participant Recruitment and Operative Procedures

This longitudinal quasi-experimental study (pre-post-intervention design) (150, 151) was conducted in the McGill University Dental Research Center. The participants in the study are edentate individuals who wished to receive 4 mini implant mandibular overdentures and were recruited from the general population of Montreal via advertisements in local magazines. The study protocol was approved by the McGill University Institutional Review Board, and an informed written consent was obtained from each study participant. Moreover, the eligibility of

the patients was assessed by clinical and radiographic examination in scheduled screening sessions. Recruited patients were included if they met the following criteria:

a) be completely edentulous, with the last tooth extraction having occurred between 6 months and 3 years previously;
b) present with existing complete dentures deemed clinically acceptable by the investigator;
c) request implant stabilization of the exiting lower conventional denture;
d) have adequate space in the anterior mandible for the placement of four MDI mini dental implants;
e) be able to maintain adequate oral hygiene and clean dentures;
f) have a systemic health status that permits minor surgical procedures;
g) have an adequate understanding of written and spoken English or French;
h) be capable of giving written informed consent.

Individuals with severe or serious illnesses or other health conditions that could affect the treatment and those who were unable to return for evaluation or study recalls were excluded from the study.

Surgical placement procedures were performed by two highly trained dentists following the standardized 3M non-invasive protocol. The O-ball attachments 3M ESPE MDI, 1.8mm - 2.1mm diameter with available lengths of 10mm, 13mm and 15mm were used in this study. Subsequently, implants were loaded with the patients' primary denture that was modified to be used with the mini implants directly after placement. In this stage, metal housings were fixed inside the existing dentures by the use of self-cured acrylic resin (secure hard pick-up kit, 3M ESPE) that also provides a smooth and comfortable surface.

Measurement Instruments

In order to assess oral health-related quality of life, the Oral Health Impact profile (OHIP- 20) questionnaire (French/English version) (90) was used (see Appendix 2). This disease-specific questionnaire measures the frequency of oral problems and their consequences on the functional and psychosocial aspects of life quality. Conceptualized by Locker in 1998 (4, 6, 83, 152), it is based on the ICF (International Classification of Function Disability and Health) framework and the WHO (World Health Organization) definition of impairment, disability and dysfunction.

OHIP-20 encompasses 20 items that record individual wellbeing within seven different domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap). Each item was rated on a five-point Likert scale (never=0, rarely=1, occasionally=2, some of the time=3 and always=4).

This response system produces a range of 0-80 for the total questionnaire score, and a lower score represents a better oral health-related quality of life. Besides the validity and reliability, which are established psychometric properties of the OHIP questionnaire (153, 154), responsiveness and sensitivity of the OHIP-20 in indicating within-patient change is a prominent characteristic of this instrument (5, 8, 149, 150, 154, 155).

The McGill Denture Satisfaction Instrument was used to collect the patients' denture satisfaction ratings. This questionnaire (see Appendix 1) contains 100-mm Visual Analogue Scale (VAS) responses and measures prosthetic satisfaction in 9 different dimensions: ease of cleaning,

general satisfaction, ability to speak, comfort, aesthetics, retention and stability, ability to chew, function and oral condition. With VAS, responses are anchored by words that clearly show the extremes; for general satisfaction, for instance, the endpoints are 'not at all satisfied' and 'extremely satisfied'.

All dimensions of this instrument are highly correlated with the general satisfaction item (82). Furthermore, the validity and responsiveness of the instrument among the patients who received conventional and implant retained over-dentures has been demonstrated in many studies (16, 82, 149).

In order to collect data for this study, participants were requested to rate the OHIP-20 and satisfaction questionnaires prior to implant placement at base line and at the 6-month recall session. In addition, a standard socio-demographic instrument was completed.

Data Analysis

The OHIP-20 total score was calculated by adding up the rating scores of all the questionnaire items. Concomitantly, the score for each particular domain was obtained by summing up the rating scores of the related questions in that domain. Moreover, change scores were determined by subtracting the baseline ratings from the 6-month follow-up ratings ($\Delta T = T1 - T0$). Therefore, negative change scores indicated improvement, while positive change scores indicated deterioration in oral health-related quality of life.

To detect any potential bias with regards the pre- and post-treatment satisfaction rating scales, measurement of the VAS for post-treatment general satisfaction was conducted by two individual researchers, and the level of agreement in this study was calculated by Kappa index,

(i.e. all the statistical analyses were conducted with the data measured by the author). Furthermore, descriptive statistics were used to present the socio-demographic characteristics of the participants. Data were shown at two points of time, baseline (T0) and the 6-month follow-up (T1). Change scores were calculated by subtracting the baseline ratings from the 6-month follow-up ratings (Δ T = T1 - T0).

To compare pre- and post-treatment OHRQoL and satisfaction scores, the Wilcoxon Signed Ranks Test was used. Furthermore, the effect size was calculated to demonstrate the magnitude of the change in pre- to post-treatment total and domain-related OHIP scores (Mean OHIPT0_Mean OHIPT1/SDT0). The Fisher's exact test was used to determine the association between the general satisfaction rating score and the socio-demographic characteristics of the participants. In order to do so, a positive change score in this domain was considered as an improvement of general satisfaction. The level of significance was set at 0.05, and data were analyzed using SPSS V.22 (SPSS Inc., IBM Corporation, Somers, NY, USA).

Table 1 –Socio-demographic Characteristics

	Category	Percentage(N)
Gender	Male	54.5%(6)
	Female	45.5%(5)
Age	Median	66 years
	Range	45-84 years
First Language	English	18.2%(2)
	French	81.8%(9)
Marital Status	Married	81.8%(9)
	Other	18.2%(2)
Life Companion	Alone	18.2%(2)
	With others	81.8%(9)
Smoking Status	Yes	0% (0)
	No	100%(11)
Level of Education	Elementary/High school	54.5%(6)
	College/university	45.5%(5)
Employment	Employed	36.4%(4)
	Unemployed	63.6%(7)
Annual Income	< $50,000	54.5%(6)
	> $50,000	45.5%(5)

Results

Baseline and 6-month post-treatment follow up questionnaires of 11 patients with complete data were assessed. The participant's mean age was 65.8 years (min 45-max 84) with 54% males and 45% females. The participants' sociodemographic characteristics are shown in Table 1.

While OHRQoL total scores demonstrated change for all participants after receiving 4 MDI over dentures, a greater percentage of patients reported an improvement, versus deterioration (63%; Table 2). Although 'Functional limitations', 'Physical pain', 'Psychological disability' and 'Social discomfort' domains did not change significantly ($P<0.05$), the change in pre- to post-treatment in the other domains, as well as in the OHRQoL total scores, were statistically significant (Table 3).

With regards to the magnitude of change, we detected medium to large changes in the OHRQoL total scores, as well as in all OHIP-20 domain scores (Table 4). The smallest pre- to post-treatment change was reported in the 'Physical pain' domain (ES=0.52), while the greatest amount of change was seen in the 'Handicap' domain (ES=1.03).

The Kappa index for satisfaction was calculated as 0.89, demonstrating an almost perfect level of inter-rater agreement (156). The majority of participants reported positive change (improved satisfaction) in all domains, excluding ease of cleaning in which 54% reported less post-treatment satisfaction (Table 5). Accordingly, all participants (100%) reported improvement in 'Retention and Stability' and 'Function' domains, and 73% of the participants reported improvement in 'general satisfaction'. However, except for 'Ease of cleaning', 'Comfort' and 'Aesthetics' ($P= 0.32, 0.09, 0.13$ respectively), which showed no significant differences, the

change in satisfaction from pre- to post-treatment in all of the six remaining domains were statistically significant (Ps<0.05).

Additionally, using pre- and post-treatment rating scores, the median change score is lowest in the 'Ease of cleaning' domain, and greatest in the 'Retention' domain (Table 6).

On the other hand, no socio-demographic factors were associated with the 'General satisfaction' improvement score (Table 7). However, compared to males, a higher percentage of females reported improvement in their 'General satisfaction' after receiving the MDI over-denture (80% vs. 66.6%).

Table 2 - OHIP-20 Domain Change Scores

	Improved N (%)	No change N (%)	Deteriorated N (%)
Oral Health Related Quality of Life Total Score	7(63)	0(0)	4(36)
Functional limitations	9 (81)	0 (0)	2(18)
Physical pain	7(63)	0(0)	4(36)
Psychological discomfort	7(63)	3(27)	1(9.09)
Physical disability	7(63)	2(18)	2(18)
Psychological disability	7(63)	1(9.09)	3(27)
Social discomfort	7(63)	3(27)	1(9.09)
Handicap	9(81)	2(18)	0(0)

Table 3 - Mean Ratings and Change Scores

	MEAN (SD)			
	Baseline (T0)	**6 months (T1)**	**Δ T**	**P Value**
Oral Health related Quality of life Total score*	44.54(26.7)	22.81(17.56)	-21.72(27.83)	0.05
Functional limitations	8.27(4.3)	5.90(3.30)	-2.36(4.73)	0.12
Physical pain	9.45(5.7)	6.45(4.94)	-3.00(6.76)	0.20
Psychological discomfort*	5.00(3.2)	2.18(2.60)	-2.81(3.45)	0.03
Physical disability*	9.63(6.0)	4.27(4.75)	-5.36(6.42)	0.02
Psychological disability	4.63(3.2)	1.90(2.25)	-2.72(4.26)	0.07
Social discomfort	3.45(3.9)	1.09(2.07)	-2.36(4.03)	0.07
Handicap*	4.09(3.0)	1.00(1.5)	-3.09(2.80)	0.008

* $P<0.05$ based on Wilcoxon Ranks Sum test

Table 4 – Total OHIP and Domain-based Effect Size

OHIP-20	EFFECT SIZE
Oral Health related Quality of life Total score	0.81
Functional limitations	0.54
Physical pain	0.52
Psychological discomfort	0.87
Physical disability	0.88
Psychological disability	0.85
Social discomfort	0.60
Handicap	1.03

Table 5 – Participants' Number and Percentage in Different Satisfaction Rating Groups

	Positive change (Improved) N (%)	No change N (%)	Negative change (Not satisfied) N (%)	P value
Ease of cleaning	5 (45)	0 (0)	6 (54)	0.328
General satisfaction*	8 (72.7)	1(9)	2 (18)	0.036
Ability to speak*	10 (90)	1 (9)	0 (0)	0.005
Comfort	9 (81)	0 (0)	2 (18)	0.09
Aesthetic	8 (72)	0 (0)	3 (27)	0.13
Retention & Stability*	11 (100)	0 (0)	0 (0)	0.003
Ability to chew*	9 (81)	0 (0)	2 (18)	0.008
Eating white bread*	10 (90)	0 (0)	1 (9)	0.004
Eating hard cheese*	10 (90)	0 (0)	1(9)	0.006
Eating raw carrots*	9 (81)	0 (0)	2 (18)	0.013
Eating sliced steak*	9 (81)	0 (0)	2 (18)	0.008
Eating raw apples*	10 (90)	0 (0)	1 (9)	0.013
Eating lettuce*	9 (81)	0 (0)	2 (18)	0.033
Function*	11(100)	0 (0)	0 (0)	0.003
Oral condition*	10 (90)	0 (0)	1 (9)	0.008

* $P<0.05$ based on Wilcoxon Ranks Sum test

Table 6 – Median Ratings, Change Scores and IQ Range for Satisfaction

	Baseline Median (IQR)	6 months Median (IQR)	Change Median (IQR)
Ease of cleaning	95 (98-87)	93 (98-85)	-1 (6--13)
General satisfaction	32 (76-17)	88 (97-59)	23 (76-0)
Ability to speak	43 (87-34)	93 (99-87)	27 (64-3)
Comfort	58 (82-21)	90 (97-70)	12 (76-4)
Aesthetics	84 (93-62)	94 (98-67)	5 (14--2)
Stability & Retention	8 (51-6)	88 (95-75)	74 (86-26)
Ability to chew Eating fresh white bread Eating hard cheese Eating raw carrots Eating sliced steak Eating raw apples Eating lettuce	12 (65-8) 25 (32-9) 21(67-10) 12 (47-2) 13 (44-2) 14 (33-2) 33 (77-15)	94 (96-64) 92 (97-68) 93 (97-63) 65 (89-39) 64 (88-25) 71 (91-47) 88 (95-56)	52 (80-16) 48 (71-21) 42 (64-25) 45 (64-5) 57 (60-8) 50 (71-17) 50 (61-2)
Function	33 (59-15)	90 (97-64)	47 (64-22)
Oral Condition	65 (77-7)	90 (97-72)	25 (75-7)

Table 7 - Association Evaluation: Socio-demographic Characteristics* and General Satisfaction Improvement

Socio-demographic Characteristics	General Satisfaction Improvement %	P Value
Gender		
Male	66.7	1.00
Female	80	
First language		
French	66.7	1.00
English	100	
Marital Status		
Married	66.7	1.00
Other	100	
Life Companion		
Living alone	50	0.49
Living with others	77.8	
Level of education		
Elementary/High school	83.3	0.54
College/University	60	
Present employment		
Employed	75	1.00
Unemployed	85.7	
Annual Revenue		
Less than 50,000$	83.3	0.54
More than 50,000$	60	

P Value based on Fisher's exact test

Discussion

When selecting treatments, patients need to have information on the benefits and impacts such therapies will have on their lives. In addition, policymakers, clinicians and health service providers require solid evidence before introducing any intervention into clinical provision. Patient Reported Outcomes (PROs) facilitate comparing and evaluating the effectiveness of different treatment modalities and new technologies. However, there are few studies in which PROs have been measured with the use of mini dental implants for oral rehabilitation (21, 138, 157, 158). This pilot study aims to assess the impact of 4-MDI overdentures on the quality of life and the level of satisfaction of edentate individuals.

Our findings show that MDI mandibular overdentures can significantly improve OHRQoL and satisfaction of edentate individuals. This result is comparable to Mundt et al.'s study, in which a significant improvement in OHRQoL in patients receiving MDI overdentures was based on responses from 129 edentate individuals using the more general OHIP-G14(157). Further, Scepanovic et al. (127) reported a significant improvement of the QoL in individuals treated with 4 MDI mandibular overdentures using the OHIP-EDENT questionnaire. Their study assessed the satisfaction of 30 edentulous patients <65 years who received new complete dentures in the first phase of study. Fifteen (15) weeks later, all patients received 4 mini dental implant mandibular over dentures, and their satisfaction was measured after the same interval. Results with the MDIs were compared with the previous patient satisfaction ratings after receiving complete dentures. Significant improvement of patient satisfaction was detected in all domains of the satisfaction instrument (82, 149), except 'Aesthetics' and 'Hygiene'; these results are similar to those found in this study.

In this study, the majority of patients reported improvement in all domains of the OHIP-20 questionnaire. However, a significant statistical change was detected only in the domains of 'Psychological discomfort ', 'Physical disability' and 'Handicap'. This could have been because of the small number in our study population. Nonetheless, it should be considered that the three largest effect sizes also were observed in these three domains. Moreover, the largest reported effect size in the Handicap domain is in harmony with Awad et al.'s findings in their multicenter clinical trial study evaluating the impact of mandibular 2-implant overdentures on OHRQoL (5).

Additionally, results of this study demonstrated that patient satisfaction is improved significantly by this modality in all aspects of assessment except for 'Ease of cleaning', 'Comfort' and 'Aesthetics'. This could be explained because the patients may have already been very satisfied with their primary dentures. Therefore, no significant change in satisfaction related to these domains post-treatment was reported (Table 6). Furthermore, contrary to some dimensions, like 'Function' or 'Ability to chew', that has additional items associated with function and chewing, 'Comfort' is assessed by only one question; 'Are you satisfied with the comfort of your lower prosthesis?'. Thus, there is no way one could determine if the respondent understood the question. The small number of participants, however, could be another explanation for this effect.

For edentulous patients, aesthetics may be mostly influenced by the maxillary denture. Thus, the finding of no difference in that factor would not be surprising. Moreover, there was no change in tooth position, color or the vertical dimension of the dentures in this study, and the participants used their own primary denture after receiving the 4 MDIs. Except for the 'Comfort' domain, these results are in agreement with the studies performed by Griffitts et al. and Tomasi et al. in

which both authors demonstrated the significant improvement of the 'Retention', 'Chewing' and 'Speaking ability' after receiving an MDI over-denture (23, 138). Yet, because the score change in the domain of 'Comfort' is not significant, it does not disagree with the results of the aforementioned studies. Our data shows over 50% satisfaction among the participants in this domain in the baseline time point, whereas in the Tomasi et al. study, poor stability and discomfort were the primary complaints of all the participants.

Our results did not show an association between any of the socio-demographic characteristics and patient satisfaction ratings. This suggests that change of satisfaction is dependent on the quality of treatment (148), also demonstrated in another implant overdenture study (8)

Although the participants' pre-evaluation and radiographic assessment, application of standardized protocol in MDI surgical procedure and use of a high-quality disease specific questionnaire increases the internal validity of the study, the small sample size, the short time distance between baseline and the follow-up session and the pre- and post- study design with no control group should be considered as limitations. Nevertheless, this pilot study could be considered as intrinsic evidence to acknowledge the efficacy of mini-dental implants in the oral rehabilitation of edentate individuals from a patients' perspective. Also, the results of this study can be used in economic assessments and cost-effectiveness evaluations of this technology. However, randomized controlled trials with larger sample sizes are needed to determine the effectiveness of this modality.

In conclusion, within the limitations of this study, our findings suggest that 4 MDI mandibular overdentures can improve the oral health-related quality of life of edentate individuals, thus supporting these as an alternative to standard-sized implants.

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CHAPTER 4.0

Conclusion

To conclude, patient's perceptions and preferences are recognized as integral elements in clinical decision-making and health policy. Similarly, evaluation and assessment of efficacy and effectiveness of any health-related intervention reasonably require considering patients' reports and viewpoints.

Moreover, oral rehabilitation has incorporated several novel interventions that can affect various aspects of the patient's life. There is adequate evidence to support the consensus that 2 implants to retain mandibular overdentures should be considered the treatment of choice over conventional dentures. However, mini dental implants may be a more acceptable treatment paradigm for edentate patients, particularly for those who are older or lack funds for more extensive implant rehabilitation.

Our findings suggest that patient satisfaction and oral health related quality of life improve significantly in edentulous patients who received 4 MDI mandibular overdentures. However, further investigations, using well-powered RCTs in which patients will be followed for a longer period of time, are required.

CHAPTER 5.0

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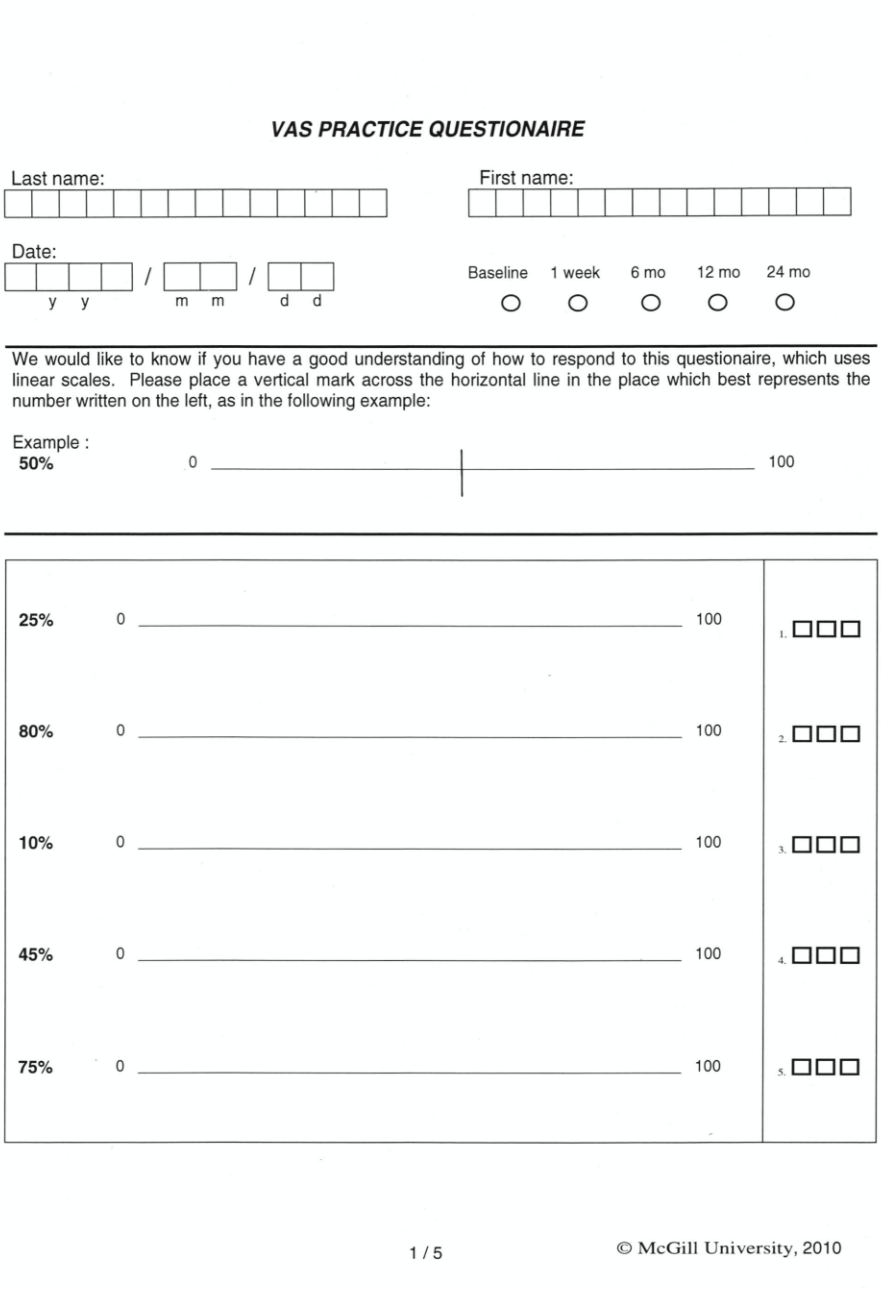
CHAPTER 6.0

APPENDICES

6.1 Appendix 1: VAS Practice Questionnaire



VAS PRACTICE QUESTIONAIRE

Last name: | | | | | | | | | | | | | | |

First name: | | | | | | | | | | | | | | |

Date: | | | | / | | | / | | |
y y m m d d

Baseline ○ 1 week ○ 6 mo ○ 12 mo ○ 24 mo ○

We would like to know if you have a good understanding of how to respond to this questionaire, which uses linear scales. Please place a vertical mark across the horizontal line in the place which best represents the number written on the left, as in the following example:

Example :
50% 0 ——|—— 100

25%	0	100	1. □□□
80%	0	100	2. □□□
10%	0	100	3. □□□
45%	0	100	4. □□□
75%	0	100	5. □□□

1 / 5

ASSESSMENT OF PROSTHESIS

Last name: | | | | | | | | | | | | | | |

First name: | | | | | | | | | | | | | | |

Date: | | | | / | | | / | | |
y y m m d d

Baseline ○ 1 week ○ 6 mo ○ 12 mo ○ 24 mo ○

We would like to know how satisfied you are with your **present** prosthesis and attachment system. Read each of the following questions and draw a vertical line on the horizontal line, where you think your answer best fits. In the case where a question doesn't apply to you, for example if you don't eat a certain type of food, write a brief explanation on the line.

1. Ease of cleaning

Please indicate how difficult it is to clean your **lower** prosthesis and mouth with the attachment system it has?

Extremely difficult _____ Not at all difficult 1. □□□

2. General satisfaction

In general, are you satisfied with your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied 2. □□□

3. Ability to speak

Please indicate how difficult it is for you to speak because of your lower prosthesis?

Extremely difficult _____ Not at all difficult 3. □□□

4. Comfort

Are you satisfied with the comfort of your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied 4. □□□

5. Aesthetics

Are you satisfied with the appearance of your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied 5. □□□

6. Retention and stability

Are you satisfied with the retention (tightness) of your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied 6. ☐☐☐

Are you satisfied with the easiness to remove your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied 7. ☐☐☐

Does your **lower** denture rocks forward and backward in your mouth when you chew?

All of the time _____ Never 8. ☐☐☐

Do you find that your lower denture comes out easily while **chewing**?

Always _____ Never 9. ☐☐☐

Do you find that your lower denture comes out easily while **speaking**?

Always _____ Never 10. ☐☐☐

Do you find that your lower denture comes out easily **with your tongue**?

Always _____ Never 11. ☐☐☐

7. Ability to chew

In general, do you find it difficult to chew food because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 12. ☐☐☐

Please indicate how difficult it is for you to eat **fresh white bread** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 13. ☐☐☐

Please indicate how difficult it is for you to eat **hard cheese** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 14. ☐☐☐

Please indicate how difficult it is for you to eat **raw carrots** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 15. ☐☐☐

Please indicate how difficult it is for you to eat **sliced steak** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 16. ☐☐☐

Please indicate how difficult it is for you to eat **raw apples** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 17. ☐☐☐

Please indicate how difficult it is for you to eat **lettuce** because of your **lower** prosthesis?

Extremely difficult _____ Not at all difficult 18. ☐☐☐

8. Function

In general, is your food well chewed before swallowing?

Badly chewed _____ Very well chewed 19. ☐☐☐

Are pieces of **fresh white bread** well chewed before swallowing?

Badly chewed _____ Very well chewed 20. ☐☐☐

Are pieces of **hard cheese** well chewed before swallowing?

Badly chewed _____ Very well chewed 21. ☐☐☐

Are pieces of **raw carrot** well chewed before swallowing?

Badly chewed _____ Very well chewed 22. ☐☐☐

Are pieces of **sliced steak** well chewed before swallowing?

Badly chewed _____ Very well chewed 23. ☐☐☐

Are pieces of **raw apple** well chewed before swallowing?

Badly chewed _____ Very well chewed 24. ☐☐☐

Are pieces of **lettuce** well chewed before swallowing?

Badly chewed _____ Very well chewed 25. ☐☐☐

9. Oral condition

In general, are you satisfied with your oral condition?

Not at all satisfied _____ Extremely satisfied 26. ☐☐☐

Do you believe that your oral condition has a negative effect on your general health?

No ○$_0$ Yes ○$_1$ 27.

If yes, why?

_____

_____

_____

_____

****

Is there any kind of problem with your upper or lower denture that you would like to report?

No ○$_0$ Yes ○$_1$ 28.

If yes, please, describe?

_____

_____

_____

_____

6.2 Appendix 2:

OHIP-20E QUESTIONNAIRE

Identification code : ☐☐☐☐☐☐☐☐☐☐

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

This questionnaire was designed to evaluate how your oral condition has affected your quality of life **during the past month**. For each of the following questions, mark the response that you feel is the best. If a question does not apply to your situation, then please indicate this just below the question.

	In the last month:	**Always**	**Most of the time**	**Some of the time**	**Occasionally**	**Rarely**	**Never**
1	Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
2	Have you had food catching in your teeth or dentures?	O1	O2	O3	O4	O5	O6
3	Have you felt that your dentures have not been fitting properly?	O1	O2	O3	O4	O5	O6
4	Have you had painful aching in your mouth?	O1	O2	O3	O4	O5	O6
5	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
6	Have you had sore spots in your mouth?	O1	O2	O3	O4	O5	O6
7	Have you had uncomfortable dentures?	O1	O2	O3	O4	O5	O6
8	Have you been worried by dental problems?	O1	O2	O3	O4	O5	O6
9	Have you been self conscious because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
10	Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
11	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
12	Have you been unable to eat with your dentures because of problems with them?	O1	O2	O3	O4	O5	O6
13	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6

	In the last month:	Always	Most of the time	Some of the time	Occasionally	Rarely	Never
14	Have you been upset because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
15	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
16	Have you avoided going out because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
17	Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
18	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
19	Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6
20	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	O1	O2	O3	O4	O5	O6

McGill University (2003)