Université de Montréal

Within-subject comparison of two- versus three-implant-assisted mandibular overdenture: Patient-based outcomes

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Within-subject comparison of two- versus three-implant-assisted mandibular overdenture: Patient-based outcomes

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RÉSUMÉ

Objectifs: Cette étude cherche à évaluer l'influence de l'ajout d'un implant additionnel dans la région médiane mandibulaire sur la perception des patients porteurs d'une prothèse préexistante assistée par deux implants.

Méthodes: Cette étude fait partie d'un essai clinique qui a été mené à l'Université de Montréal. Dix-sept personnes édentées (âge moyen de 61,9 ± 6,6 ans) ont reçu trois implants dans la région mandibulaire interforaminale. Deux implants ont été place près des trous mentonniers et le troisième au niveau de la ligne médiane. Au début de l'essai, les sujets ont été appareillés d'une prothèse de recouvrement mandibulaire assistée par les deux implants distaux. Ces implants étaient coiffés par des attaches individuelles Locator®. Le troisième implant n'a pas été mis en charge initialement et il est resté sans attache pour deux ans. Après cette période, une attache Locator a été installée sur le troisième implant et la prothèse de recouvrement a été modifiée pour accommoder ce mécanisme de rétention additionnel. Les mouvements antéropostérieurs de la prothèse tel que perçus par les patients ainsi que ceux évalués en cliniques ont été mesurés avant et après cette modification. La satisfaction des patients, leurs perceptions et leurs attentes vis-à-vis les prothèses mandibulaires ainsi que la volonté de payer ont été évaluées. La collecte de données a été effectuée à l'aide de questionnaires auto administré validés, à la suite de la

modification et après six semaines d'utilisation. Des données sociodémographiques ont également été recueillies. Des statistiques descriptives et les essais non paramétriques ont été employés pour l'analyse statistique.

Résultats: Les résultats ont indiqué une diminution statistiquement significative dans le mouvement antéropostérieur de la prothèse mandibulaire (p = 0,005) tel qu'évalué en clinique. Les patients ont rapporté une amélioration au niveau de la stabilité de la prothèse mandibulaire (p = 0,005), de même qu'au niveau de leur capacité à parler (p = 0,011) et à mastiquer les aliments durs (p = 0,012).

L'ajout d'un troisième implant a répondu aux attentes des patients en ce qui concerne la stabilité (pour 94 % des patients), la rétention (100 %) et le confort (82,4%) de la prothèse mandibulaire. Sur une période de six semaines, la prothèse de recouvrement mandibulaire assistée par trois implants a contribué à l'augmentation de la satisfaction générale des patients, mais cette amélioration n'était pas statistiquement significative. Environ 80 % des patients recommanderaient ce type de prothèse à leurs pairs, mais seulement 47 % d'entre eux accepteraient de payer l'augmentation du coût de traitement associée à la pose d'un troisième implant.

Conclusions: L'ajout d'un troisième implant dans la région médiane d’une prothèse préexistante assistée par deux implants a permis d'obtenir de meilleurs résultats au niveau de l’expérience du patient. Cependant, le coût supplémentaire du traitement peut influencer les choix du patient.

Mots-clés: Essai clinique, implant dentaire, prothèse de recouvrement mandibulaire implanto-assistée, résultats basés sur les patients.

ABSTRACT

Objectives: This study aims to assess the impact of an additional midline implant to support an existing mandibular two-implant overdenture, on patient-based outcomes (patients' satisfaction and expectations).

Methods: This study was nested within a previous clinical trial conducted at the Université de Montréal. Seventeen edentulous individuals (mean age: 61.9 ± 6.6 years) received three threaded implants in the interforaminal mandibular area and a mandibular overdenture using two Locator® attachments. The midline implant was left unloaded over a two-year period. At the two-year follow-up, using a standard protocol, the third implant received a Locator® attachment and the overdenture was converted to a three-implant-assisted overdenture. The clinical and perceived anterior–posterior movements of mandibular prostheses were measured before and after the conversion. Patients' expectation and satisfaction in regard to mandibular prosthesis as well as their willingness to pay the cost for the conversion were evaluated by using validated self-administered questionnaires. Data collection was conducted at baseline and after six weeks of wearing the converted mandibular prosthesis.

Socio-demographic data were also collected. Descriptive statistics and non-paramteric tests were used for statistical analysis.

Results: Data analysis revealed a statistically significant decrease in the anterior–posterior movement ($p = 0.005$) of overdenture as evaluated by clinicians. Study participants reported an increase in perceived stability of the overdenture ($p = 0.005$), and in their ability to speak ($p = 0.011$) and to chew hard food ($p = 0.012$). The addition of a third implant met the expectations of 94% of patients in regard to lower denture stability, 100% for retention, and 82.4% for comfort. The 3-implant-assisted mandibular overdenture increased patients' general satisfaction over a short period of time, but this improvement was not statistically significant. About 80% of patients would recommend this type of prosthesis to their peers but only 47% of them would agree to pay a large increase in the cost of treatment compared to 2-implant overdenture.

Conclusions: The addition of a midline third implant to an existing 2-mandibular-implant overdenture will lead to better patient-based outcomes. However, the additional cost of the treatment may influence patient preferences.

Keywords: Clinical trial, Dental implants, Overdentures, Mandibular prosthesis, Patient satisfaction.

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LIST OF SYMBOLS AND ABBREVIATIONS

CD	Conventional Complete Denture
CI	Confidence Interval
ES	Effect Size
FDA	Functional Denture Assessment
IOD	Implant Overdenture
IOM	Institute of Medicine
ISO	Implant-supported Overdentures
IT	Torque on Insertion
ITSO	Implant-tissue-supported Overdentures
MIACRP	Mandibular Implant-assisted Complete Removable Prostheses
MIAO	Mandibular Implant-assisted Overdentures
Ncm	Newton centimeter (Unit of measurement)
OHRQoL	Oral Health-Related Quality of Life
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measures
SD	Standard Deviation
SORT	Strength-of-Recommendation Taxonomy
SPSS	Statistical Package for the Social Sciences
VAS	Visual Analogue Scale
WTP	Willingness To Pay
%	Percentage

DEDICATION

This thesis dedicated to my husband Mohammad, without whom it would not have been completed.

I truly remember when you told me: "Aminah just go on, you'll find me always supporting you, till the end" . . . and . . . here I am at "the End"! and I am still embraced in your love, care, and support.

Thank you for always believing in me and pushing me forward to achieve my dream, thank you for continually encouraging me during the challenges of graduate school and of life, at the expense of your own comfort and professional plans.

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CHAPTER 1: LITERATURE REVIEW

1.1 INTRODUCTION

Since 1990, the evidence-based dentistry approach has been adopted by many clinicians to avoid negligent care, to ensure the quality of health care, and to obtain predictable treatment outcomes (1-3). Evidence-based dentistry is defined by the American Dental Association as: "an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences"(4).

Within this context, in the past two decades, patient-based outcomes have been used widely in prosthodontics research to provide high-quality evidence on the efficacy and effectiveness of a variety of prosthetic treatments (5, 6). In this regard, implant-assisted removable prostheses have been reported to increase patients' satisfaction and to improve patients' well-being and quality of life through optimizing the functional capacity of the oral cavity and addressing the psychological and social needs of edentate individuals (6-8). Despite the increase use of the implant-overdenture in dental practices, evidence on the impact of the three-implant-assisted overdentures on patient-reported outcomes, especially with universal resilient attachments such as Locators, remains scarce. This chapter will provide a brief review of the literature on the key

aspects of mandibular implant-assisted removable prosthesis as well as patient-based outcomes, to orient the reader toward the research gap leading to this master research project.

1.2 MANDIBULAR IMPLANT-ASSISTED REMOVABLE PROSTHESES

Dental implants have been used successfully to improve the clinical outcome of removable complete dentures, especially in the mandible. They can help improve the support, the retention and the stability of prostheses. Mandibular implant-assisted complete removable prostheses (MIACRP) or mandibular implant-assisted overdentures (MIAO) are prostheses that completely cover the mandibular arch and are used in conjunction with dental implants. If these prostheses can all be removed by patients, their prosthetic design can, however, vary significantly (9-12). So, it is necessary to classify them according to additional characteristic. Simon and Yanase (13) suggested that the nature of the support provided should be used to classify this type of prostheses, since most implant prostheses are inherently retained and stabilized by their respective implants. They underlined that conventional removable prostheses have been traditionally classified this way. Therefore mandibular implant-assisted complete removable prostheses can be divided in two types:

1. Implant-supported overdentures (ISO) are prostheses that gain their entire support from dental implants. They are assisted by a significant number of implants, four or more. They are

generally connected to a implant superstructure such as a rigid bar with cantilever distal extensions (11, 13), since implants can hardly be placed in the posterior mandibular zones.

2. Implant-tissue-supported overdentures (ITSO) are prostheses that obtain their support from a combination intra-oral tissues and dental implants. They are therefore assisted by a smaller number of implants, three or less. They can be connected, in the mandibular anterior region, to an implant superstructure such as a resilient bar with no or limited cantilever extension. They can also be connected to individual abutments. This type of overdenture obtains its posterior support from the mucosa (11).

Because these significant differences in implant support, the specific characteristics in terms of prosthetic design of each treatment option should take into consideration when planning for mandibular assisted-implant overdentures.

1.3 PROSTHETIC DESIGN

The design of the prosthesis must be considered before the placement of implants and in the treatment planning phase (14). When planning the prosthetic design of an implant-assisted overdenture, several factors should be considered to achieve a successful treatment (11, 12).

These factors primarily include patients' general health, needs, preferences, and expectations of the treatment as well as their financial status and their willingness to pay for the treatment (10).

Mandibular implant-assisted overdentures are often the choice of edentulous patients, especially elders, for several reasons. They could require fewer implants and thus are generally less expensive compared to the implant-assisted fixed prostheses (15-17). They restore more easily the lost hard tissues and support the labial soft tissues thereby adequately addressing the aesthetic demands of the patient (18, 19). Moreover, their removability facilitates the oral health care maintenance and oral hygiene access (19-22); especially among elder and frail individuals where the fine motor skills could be diminished (23). In medically compromised patients, implant-tissue-supported overdentures are preferable because of shorter surgical procedures, and less complex treatment (19, 20).

Secondly, the clinician's expertise and ability to provide the treatment is an important factor in the selection of the type of prosthesis and should be discussed with the patient. For dentists, management of care is usually easier with mandibular implant-assisted removable prosthesis compared to the fixed counterpart in terms of the complexity of the treatment as well as long-term complications and maintenance (24).

Finally, anatomical and prosthetic factors such as the quantity and quality of available bone, the amount of keratinized tissue, the need for facial support, available inter-arch space, intermaxillary relation, as well as the choice of numbers and positions of implants and associated supra-structure should be considered in the prosthetic design (11, 18, 25).

1.3.1 Anatomical factors

Although the amount of available bone is an important factor in the prosthetic design, it is less critical for the implant-tissue-supported overdentures; since they require fewer implants, and bone augmentation procedures may be less likely required than with implant-supported overdentures (20).

In addition, an implant-assisted overdenture is indicated for patients with advanced ridge resorption, lack of muscle tone, and an excessively concave profile since it provides optimal facial support and easy hygiene access (11, 14, 19, 20, 26). Furthermore, in patients with a wide disparity in size and position of the maxillary and mandibular ridges (severe class II and class III), or in patients with advanced ridge resorption, it is easier to restore the occlusion with implant-assisted overdenture (14, 27).

1.3.2 Number and position of implants

The number and distribution of implants over the arch are key aspects of the prosthetic design since they determine the level of retention and stability of the prosthesis, influence stress distribution, and thus play an important role in the success and survival of implants as well as the associated biomechanical complications (28-30). An optimal stress distribution reduces denture movement and the forces on the implants (31).

A range of one to four implants can be considered in the design of the mandibular implant-assisted removable prosthesis (32). Factors such as shape and the size of the mandibular ridges as well as the force transmitted by the opposing jaw play an important role in the choice of number of implants and their position over the arch (33). A large U-shaped mandibular ridge often allows the placement of two to four implants in the anterior region of mandibular ridge and provides a solid infrastructure for a bar attachment (9, 29, 34). For a V-shaped ridge, three to four implants could be considered (29, 34, 35).

A minimum number of implants should be considered in the design of the prosthesis when a minimally invasive treatment or a treatment with a lower cost is required. The mandibular one- or two-implant-assisted overdentures could be considered especially in edentulous individuals with low socio-economic status (36-38). This type of overdenture is also beneficial in patients with mental impairment, or with diminished manual dexterity (11).

A number of in-vitro studies have examined the relation between the number of implants and the transmitted stress around the implants (28, 39, 40). Topkaya and Solmaz (41) used finite element analysis to examine the effect of the loading sites and the number of implants on stress distribution around implants in two models of mandibular overdentures. In those models, prostheses were assisted by two or four implants with ball anchor abutments. Their results showed that, under different loading conditions, the amount of stress on the four-implant-assisted

overdentures models was less than on the two-implant-assisted designs. Thereby, increasing the number of the implants would lead to more force distribution.

Liu et al. (42) conducted a three-dimensional finite element analysis to examine strain distribution in cortical bone around implants, stress in the abutments, and the denture stability of various types of mandibular-implant-assisted overdentures under different loading. Their results confirmed the previous findings of clinical studies showing no effect of the number of implants in peri-implant bone resorption (43, 44). However, in this study under the vertical loading of the anterior region, the two-implant-assisted overdenture showed more rotational movement and higher stress in the abutments compared to one- and three-implant-assisted overdentures. The three-implant-assisted overdenture did not show any damaging strain concentration in the peri-implant bone of the middle implant. The authors concluded that a midline implant could be added in patients wearing a two-implant-assisted overdentures and who are complaining of denture rotation. This third implant would preclude prosthesis movement around the fulcrum line. However, analyses based on in-vitro studies can deviate from many aspects of a clinical situation, and evidence from clinical trials is necessary in order to provide solid practice guidelines.

A number of prospective clinical trials as well as systematic reviews have been conducted to compare clinical outcomes for mandibular implant-overdentures assisted by one, two, three and

four implants (24, 45-51). In general, research findings showed that although four implants may better protect the mandible from posterior bone resorption and provide better support and force distribution for mandibular overdenture, a decrease in the number of implants does not compromise implant survival or patient satisfaction (43, 44, 48, 50, 52, 53). A systematic review conducted by Lee et al. (30) in 2012, including 11 clinical trials, concluded that implant survival rate and patient satisfaction with mandibular overdentures is high regardless of the number of implants. Furthermore, denture maintenance does not seem to be influenced greatly by number of implants.

A recent systematic review and meta-analysis conducted by Srinivasan et al. (51) summarized 28 prospective studies and two randomized controlled trials to compare the survival rate of mandibular one- versus two-implant-assisted overdentures. Their results did not show any significant difference between these two designs of overdenture. However, the authors recommended to properly consider long-term observation of prosthetic as well as patient-related outcomes measures before treating their patients with one-implant-tissue-supported overedentures.

Moreover, this systematic review concluded that there is a research gap in long-term studies for the development of practice guidelines.

In 2002, the two-implant-assisted mandibular overdenture was proposed as the first choice of

prosthodontic treatment for the edentulous mandible (54), and there is overwhelming evidence for its effectiveness and efficacy in terms of clinical and patient-based outcomes (8, 43, 55-58). However, despite this evidence, the use of mandibular overdenture assisted by two implants has some limitations and is not recommended in certain cases (59). These include patients with V-shaped or severely resorbed ridges, in presence of high occlusal force and if more retention is required due to high muscle attachment (12, 18, 60).

In the study conducted by Kimoto et al. (61) patients with mandibular two-implant-assisted overdentures reported a rotational movement of their prosthesis with a negative impact on their chewing ability. This statement has been supported by an in-vitro study revealed that rotational movement can cause higher strain on the implants, or on surrounding tissue (42).

Sadowsky et al. (12) and Geckili et al. (59) have suggested that adding a third implant in the mandibular symphyseal area can increase the stability and retention of two-implant overdenture. Moreover, according to a recent practice-based clinical study, edentate individuals wearing three-implant overdentures reported a negligible amount of rotational movement around the fulcrum line of the prosthesis, and the majority of the patients were totally satisfied with their prosthesis (62).

1.3.3 Attachment systems

Another factor that should be considered in the prosthetic design of an implant-assisted overdenture is the implant attachment system. According to the Glossary of Prosthodontics Terms, an attachment is "a mechanical device for the fixation, retention, and stabilization of the prosthesis" (63).

A wide variety of attachment systems have been introduced for mandibular implant overdenture (64). There are four types that are more commonly used (65). These include studs, bar and clips, magnets, and telescopic attachments. The available attachments have different levels of resilience based on the range of movement allowed between the abutment and the prosthesis (26, 34).

Resilient attachments, such as ball attachments, round or ovoid short bar with clips, Locators, and magnets (26) permit prosthesis movement in pre-set directions (65), thereby protecting the implants from overload by providing better stress distribution (64, 66). However, since these types of attachment transfer the load to the posterior areas of mandibular bone, they may lead to bone resorption in the posterior alveolar ridge (67). Different degrees of tissue-ward movement are allowed with bar systems, depending on their cross-sectional shape (34, 68). In general, rigid attachments (26) do not allow any denture movement and thus the load is mainly transfer to the implants (65, 66).

The most commonly employed attachments with implant-assisted overdenture are stud attachments such as ball, Locator, and O-ring attachments (65). Generally, stud attachments are more affordable than bar attachments (69) and require minimal maintenance (68, 70). All of the stud attachments yield vertical and hinge movement (34, 65), except the Locator, which provides nearly all types of denture movement (universal resilience). Stud attachment is composed of a housing (female component) that is embedded in the fitting surface of the denture and frictionally retained over the stud (male component) that is attached to the abutment or implant (64, 65). Stud attachments are ideal for patients with a narrow or V-shaped ridge where using bars may interfere with tongue movement (67). With this type of attachment, implant parallelism is critical (71), since it facilitates prosthesis insertion and removal as well as reducing the wear on the attachment components (68, 72, 73). Ball attachments are among the most commonly used stud attachment systems because they are practical, have relatively low cost as well as require less chair-side time (64). However, the O-ring attachment, which has a rubber retentive element, is prone to wear easily and loses its retention gradually over a short period of time, particularly with non-parallel implants (64, 74). The Locator attachments were introduced by Zest Anchors (Escondido, CA, USA) in 2001 (75). Since then this system has been widely used with implant-assisted overdentures (26, 65, 76). The increase use of Locator attachment system has been referred to its favourable features such as low cost, self-alignment with dual retention,

variety in the retentive range, low profile height, and ease of maintenance, repair, and replacement (77).

Bar attachments offer considerable stability in cases with a severely resorbed ridge (67), and they are recommended for multiple, non-parallel implants (70). However, patients with these systems could experience challenges in maintaining adequate oral hygiene (69), and there is the potential for soft tissue complications such as mucosal hyperplasia (26). Additional disadvantages of these attachments are the high cost and the technical complications associated with them (70).

With the wide variety of attachment systems available, the selection of the proper system could be challenging for clinicians (78). The choice of attachment for an implant overdenture depends on the amount of available bone, the patient's prosthetic expectation and financial status, and the clinician's experience (65). Implant position, inter-implant distance and parallelism of the implants, and the available inter-arch space should also be considered in the selection of an adequate attachment system (26, 64) during the treatment planning phase (26, 65, 78, 79).

An adequate restorative space should be taken into consideration in the prosthetic design to ensure a physiological contour and an acceptable aesthetic and occlusion for the prosthesis. The minimum vertical space requirement for an implant overdenture ranges from 8.5 to 13 mm, depending on the choice of the superstructure (10, 14, 34, 73).

The minimum prosthetic space for bar-supported overdentures is 13–14 mm (26, 69), whereas for Locator attachments at least 8.5 mm is required, and for implant overdenture retained with other freestanding attachments, such as ball attachment, the required space is about 10–12 mm (69, 73, 80). Attachment systems have a significant impact on the movement of the implant overdenture as well as the amount of load transmitted to its supporting implants (81).

Yoda et al. (81) evaluated, in an in-vitro experiment, the effect of three attachment types (Locators, ball attachments and round bars) on the load distribution to implant and residual ridge using two-implant overdenture models. The results of their study showed that the load on implants was significantly higher with ball attachments; while on the residual ridge the highest load was reported with the round bars followed by Locator and ball attachments. These findings also confirmed the results of other studies in which, for patients wearing two- and four-implant overdentures, the transmitted stress to their mucosa was greater with ball attachments than with Locators (82).

Several clinical trials have examined the clinical outcomes of attachment systems used for mandibular implant-assisted overdentures in terms of implant survival rate (26, 79, 83), peri-implant bone loss (26, 29, 45, 79, 84), retentive capacity (26, 85), stress distribution on the implants and surrounding bone (26, 29, 79), as well as patient satisfaction (26, 78, 79, 83-85).

In general, the results of these studies showed that there is no difference in implant survival rate, peri-implant bone loss, stress distribution, and patient satisfaction between the attachment systems (26, 29, 78, 83). However, some studies showed that patients' satisfaction with magnet attachment systems is lower in comparison to other designs (26). Furthermore, these attachments showed susceptibility to corrosion in the oral environment, which could influence their retention strength (66).

The attachment systems vary in their retentive capacity (86). Generally, a force between 5 and 8 Newtons is required for the retention of an implant overdenture (87). However, coordinating the retentive characteristics of the attachment system with the patient's needs is an important factor in treatment success and patient satisfaction (88). In patients with poor manual dexterity skills, less retention is usually needed (88).

The retention of the attachment systems changes over time due to the micro- and macro-movement between the retentive surfaces of an attachment during mastication and removal of the prosthesis (73, 79, 89). Abi Nader et al. (90) assessed the effect of simulated mastication in an in-vitro study on the retentive capacity of two types of stud attachment systems, ball and locator. The retention forces were measured at baseline and after 400,000 simulated masticatory loads. Although at baseline the retention of the ball attachment was lower than the locators, during the experiment it remains stable under the simulated mastication. No significant loss of retention has

been shown with ball attachment over the time. However, with Locator attachment, the simulated mastication resulted in alterations of the nylon inserts, which led to the loss of more than 40% of its initial retentive strength.

The retentive strength of attachment systems is also related to implant parallelism. A divergence of higher than 10 degrees can lead to excessive wear on attachments and decreased retention (79, 91). Although the locator attachments have the ability to accommodate implant divergence of up to 40 degrees (77), the labial–lingual inter-implant angulation found to have a negative effect on its retention. In a prospective clinical study conducted by Jabbour et al. (92) the impact of inter-implant angulation (sagittal and coronal) on the retention of two attachment systems, ball and locator, has been evaluated at different time points during a year of wearing two-implant-assisted overdenture. It was found that the inter-implant angulation has a significantly higher impact on the retention of locator than of ball attachments.

1.4 PATIENT-REPORTED OUTCOMES

1.4.1 Definition and importance in research

Patient-centered care has been defined by the Institute of Medicine (93) as "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions" (93).

This care approach has been acknowledged by the Institute of Medicine (93) for providing high quality health care, and several studies have demonstrated that use of the patient-centered approach will lead to treatment adherence and better health outcomes (94). Health care research has highlighted the importance of evaluation of health care interventions from the patient's perspective (95-97). According to the Strength-of-Recommendation Taxonomy (SORT), studies that provide patient-oriented evidence have the highest rank in the hierarchy of evidence since the results of these studies lead to solid clinical guideline (98).

Patient-oriented research assumed greater importance in the middle of the 20th century when a new definition of health was provided by the World Health Organization: "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (99). Consequently, the evaluation of the treatment effectiveness shifted towards the outcomes that show social and psychological dimensions of health (100). Ebell et al. (98), has defined patient-reported outcomes as " the outcomes that matter to patients and help them live longer or better

lives, including reduced morbidity, reduced mortality, symptom improvement, improved quality of life, or lower cost".

These outcomes complement disease-oriented outcomes for the evaluation of a treatment, and are not necessarily correlated with them (96, 101). Disease-oriented outcomes are based on the assessment of physiological and clinical indicators of health and oral health or their surrogates (98). Although these outcomes are very important, they do not provide any information about patients' perceptions and needs regarding their health and oral health (102).

The application of patient-reported outcomes in the field of prosthodontics has been increased in the last decades (5, 7, 55, 103). According to a systematic review performed by McGrath et al. (5), the patient-reported outcome most used in this research field is patient satisfaction, followed by physical, social, and psychological impacts of prosthetic treatments on oral health, general health, and well-being. A systematic review conduced by Emami's research group in 2014 (104) examined the research outcomes of interest in the field of removable prosthodontics. The review showed that disease-oriented outcomes were the most frequently reported outcomes and highlighted the need for patient-reported evidence in this field.

1.4.2 Patients' satisfaction

One of the most important and commonly used patient-reported outcomes is patient satisfaction (105). Patient satisfaction is a multi-dimensional construct that can be influenced by many

factors such as the individual's values, expectations, and previous experiences with the treatment (106, 107). According to Mohan et al.(108), patient satisfaction is the patient's emotions, feelings, and perceptions, that arise from his/her appraisal of the provided health care. Measuring patient satisfaction is important because it can be related to other health and oral health outcomes (109).

In the field of removable prosthodontics, several systematic reviews have been published on the effect of mandibular implant-assisted prosthesis on patient satisfactions (8, 56, 103, 110, 111). The results are similar and suggest that mandibular implant overdentures improve the patients' satisfaction and oral health related quality of life mainly because they improve retention and stability of the prosthesis as well as chewing capacity, when compared to conventional dentures (103).

Michaud et al. (109), in a randomized clinical trial of a sample of 219 edentate patients, examined the level of association between patient satisfaction with the prosthesis and oral health-related quality of life (OHRQoL), as well as those dimensions of satisfaction that best predicted OHRQoL. A significant positive correlation was found between oral health-related quality of life and different aspects of denture satisfaction regardless of the type of the prosthesis (implant-assisted overdenture or conventional denture). Satisfaction with chewing abilities and general oral condition were the best predictors of OHRQoL and explained 46.4% of improvement in oral

health-related quality of life.

According to a clinical trial conducted in Canada by Awad and Feine in 1998 (110), patients' sex, ratings of comfort, esthetics, stability, and ability to chew and to speak are significant contributors of patient satisfaction and could explain 89% of the variation in ratings of satisfaction. Furthermore, this study showed that the rating of satisfaction was higher among those individuals who considered chewing performance as the key element of patient satisfaction with the prosthesis. Furthermore, women showed higher level of satisfaction than men, which has been explained by the sex-difference in musculature and the amplitude of the biting force.

Emami et al. research group conducted a meta-analysis to examine the efficacy of mandibular implant-retained overdentures on patient satisfaction (7). This meta-analysis included six randomized controlled trials with a total of 558 patients, 322 with two-implant overdentures and 266 with conventional dentures. Results showed that patients wearing implant overdentures were more satisfied than those wearing conventional dentures (effect size 0.80, 95% CI: 0.36 to 1.24). However, a statistical heterogeneity was found due to the type of patient recruitment, which reflected the patient characteristics and oral conditions of the patients. The same research group updated this meta-analysis seven years later including four new trials (55). The updated version showed results similar to the previous one but with larger effect size (0.87, 95% CI: 0.55 to 1.19). However, the authors concluded that health status and poor oral condition might reduce

the magnitude of effect. This conclusion is in line with studies that showed implant overdentures are more beneficial for patients with severe alveolar atrophy and poor denture adaptability (112, 113).

Patients' satisfaction in relation to the number of implants as well as type of attachment in mandibular implant-assisted overdentures has also been examined in various studies (24, 30, 39, 48, 53, 114-116). Nogueira et al. (117) reviewed the impact of single-implant mandibular overdentures on patient satisfaction and concluded that the number of implants is not a predictor of patient satisfaction. Wismeijer et al. (53) compared patient satisfaction in 108 patients wearing three types of implant-assisted prosthesis (two-implant overdenture with ball attachments, two-implant overdentures with a single bar attachment, and four- implant supported overdenture with a triple bar attachment) over a period of 16 months. This randomized clinical trial did not find a statistically significant difference between these three treatment options. Systematic reviews conducted by Klemetti (39), Lee et al. (30), and Roccuzzo et al. (48) have also shown that the level of patient satisfaction in regard to implant-assisted prosthesis is not associated with the number of implants. However, a recent pilot clinical trial conducted by Bhat et al. (114) showed a positive association between patient satisfaction and number of implants. In this trial, the same group of patients (n=10) rated their satisfaction with conventional denture, and one-, two-, and three-implant mandibular overdentures during a sequential implant loading process. The study's

results showed that the level of patient satisfaction was similar for conventional denture and single-implant overdenture. However, the addition of implants increased patients' masticatory efficiency and ability to chew. In this study patients had a higher level of satisfaction with three-implant overdentures. These results confirmed the results of a practice-based study, where 135 edentate participants received mandibular three-implant overdentures and the majority of them showed extreme satisfaction with their prosthesis (62).

1.4.3 Patients' expectation

Patients' expectation of a treatment or care is defined as the anticipation or the beliefs of the patient about the future consequences that they will experience or encounter during a treatment or health care services (118). According to McKinley et al. (119), patients' expectation of the care has two dimensions: 1) the expectation of patients as a result of their own or others' previous experiences, and 2) the patients' hope for the care they will receive.

Laferton et al. (120) recently reviewed expectation concepts and theories (120). They found three theories related to patients' satisfaction:

1) Social and cognitive learning theory: The beliefs, or values, that result form cognitive processes are modified by experiences, or "social learning" (121). This theory distinguishes between a) behavior-outcome expectations "which express the (subjective) likelihood that a specific outcome will follow a given action" (e.g., in the context of this thesis, wearing an

implant-overdenture will lead to health benefits), and b) self-efficacy expectations, “which express an individual’s expectation of being capable of executing a certain action” (e.g., ability to adapt to conventional denture) (120).

2) Response expectancy theory: This theory differentiates between stimulus expectancies (external outcomes, such as increasing social interaction with wearing a stable prosthesis) and response expectancies (internal outcomes, such as satisfaction) (122, 123) .

3) The common-sense model of illness representations: This theory refers to patients’ perception of their illness, including causes, symptoms, and whether they can control the condition by themselves (such as adaption to the prosthesis) or if they need treatment to control their condition or disease.

In general, evidence shows that fulfillment of patients' expectation of a treatment is associated with their higher satisfaction with the care and with greater adherence to the treatment (124-127). It has been also reported that patients’ expectations can explain up to 25% of the variance in the satisfaction level (128). Furthermore, the association between patient expectations and satisfaction can be moderated by patients’ characteristics, the cost of treatment, communication with the clinicians, as well as the delivered information. (126). Therefore, providing reliable and valid information on the treatment modalities and their limitations prevents patients having unrealistic ideas about the treatment outcomes and subsequent dissatisfaction based on unmet

expectations (126, 129).

A number of clinical studies have been conducted to examine patients' expectations and their association with the level of satisfaction with prosthetic treatments (106, 107, 130, 131). In 2011, Baracat et al. (130) conducted a clinical study (n=50) in Brazil to examine if patients' expectations in regard to the functional and esthetic aspects of implant-assisted treatment were correlated with their satisfaction with care. The results showed that the patients' satisfaction with the treatment exceeded their expectations. The authors related these results to the patients' previous negative experiences with dental treatment, their low oral health condition and their other characteristics. The study conducted by Menassa et al. (107) in Canada on patients' expectations and satisfaction in regard to immediate loading of two-implant mandibular overdenture showed that the immediate loading process met the patients' expectations and satisfied them because of rapid return to oral function.

Yao et al. (132) conducted a systematic review to provide evidence on the impact of patients' expectations on implant-assisted treatment outcomes. This systematic review found only 10 relevant studies on this topic, which were published between 1999 and 2013. The review confirmed that unrealistic expectations before the intervention may lead to patients' dissatisfaction with final treatment outcomes. In 2013, Gaspar et al. (106) studied the correlation between patients' satisfaction and previous experience, patients' expectations, as well as the

number of post-delivery adjustments in Brazilian patients who received a new complete denture. The study results showed that previous experiences had a slight effect on patients' expectations and satisfaction with the provided treatment, and that patient satisfaction was related to treatment outcomes such as number of post-delivery adjustments. Those patients who had fewer post-delivery adjustments were more satisfied with the treatment. In 2013, De Siqueira et al. (131), evaluated patients' expectations and satisfaction with treatment in 44 patients who received removable partial dentures. The results of this study also confirmed those of the pervious study (106), that patients' satisfaction with the treatment is influenced by various factors such as the quality of care, the patient's characteristics, and the type of prosthetic treatments (106).

1.4.4 Patient-reported outcome measures

Patient-reported outcome measures (PROMs) have been defined by Dawson et al. (133) as measures that assess individuals' perceptions of their own health status, quality of life, physical function, psychological well-being, social well-being, role activities, cognitive functioning, and satisfaction with care (134). These instruments also help to evaluate the effect of the treatment from aspects that are not objectively perceptible (100).

The PROMs are mainly classified into two broad categories (133, 135):

1) Generic measures: are multidimensional measurement instruments that can be used to measure physical, social, and emotional dimensions of health in diverse populations, either healthy or with a broad range of medical conditions. These measures can be used to assess individuals' health perceptions in wide range of diseases (136-138), thus they facilitate the comparison of burden of disease (139). However, the generic instruments lack high sensitivity, are less precise and are not responsive to small changes related to specific diseases (134, 140). A well-known example of such instruments is the 36-item Short From (SF-36) (141). This instrument was designed to measure the concept of health status (mental and physical) in the Medical Outcomes Study (MOS) (141). The SF-36 is a multi-item scale that assesses eight health concepts: physical functioning, role limitations due to physical health problems, social functioning, role limitations due to emotional problems, pain, mental health, vitality, and general health.

2) Disease-specific or condition-specific measures: these instruments are used to assess patients' perceptions of specific medical conditions or diseases. They include questions that are relevant to specific diseases; therefore they are highly sensitive (139, 142). However, the use of these instruments doesn't allow comparing the burden of different diseases or the effects of a broad range of treatments.

The validity and the reliability of patient-reported outcome measures are factors that should be considered in the selection of appropriate measurement instruments (143). In the field of

prosthodontics, several types of measure have been developed and have been validated in several languages to evaluate the impact of various prosthetic treatments on patient-based outcomes (143). The Oral Health Impact Profile (OHIP) (144) is among the most common instruments in this field. This questionnaire measures the oral health-related quality of life (144) and has different versions such as the full item version (OHIP-49), the short version (OHIP 14), and OHIP-19 (OHIP-EDENT) (145).

1.4.5 Patients' expectations and satisfaction measurement instruments

In the field of prosthodontics, qualitative and quantitative approaches can be used to measure patients' expectations (107, 146, 147) and satisfaction (62, 107, 109, 114, 148-150). The choice of methodology and adequate measurement instrument is dependent on the study objectives and design, and study intervention (151).

In general, in the qualitative approach audio-recorded semi-structured individual interviews or focus group discussions are used to explore patients' perceptions of treatment (146-148). In the quantitative approach data are collected using questionnaires (107, 109, 130, 152, 153). These questionnaires could be in different formats such as the visual analogue scale (VAS) or Likert scale.

Visual analogue scales (VAS) are practical, easy, and rapidly administered tools that have been used widely in clinical and research settings to measure a wide range of subjective phenomena

(154). In comparison with the Likert scales, the time needed to complete this type of questionnaire is about 30% less (155). VAS can be used in different clinical settings and with a wide range of populations, particularly when within-individual changes are the subject of interest (156). However, this type of questionnaire has been criticized in terms of precision and value for intra-individual comparisons (157). Elderly patients with impaired cognition may face difficulty in understanding and completing this type of scale (156). To decrease potential measurement error, it has been recommended to supervise the data collection or using an interviewing technique while applying this instrument.

The McGill Denture Satisfaction Instrument is the tool most commonly used to measure patients' satisfaction with prosthesis and its various dimensions (8, 100, 109, 110, 153). These dimensions include: ease of cleaning, ability to speak, comfort, esthetics, stability, chewing ability, general satisfaction, and oral condition (100, 158). The patients rate their satisfaction on a 100 mm VAS, which is anchored by the words "not at all satisfied" and "extremely satisfied" (109, 110, 152).

Likert scales have been also used to measure the patient satisfaction with the prosthesis (159-162). These questionnaires are easy for patients to understand and complete by the patients, as well as being easy for researchers to compute and analyse (163, 164). However, some researchers choose to use the VAS to avoid a bias in analysis that may result from inconstant

differences between categories in the Likert scale. For instance the difference between "excellent" and "very good" is not necessarily equivalent to that between "good" and "moderate" (165).

Although patients' expectations have been acknowledged to be an important measure in clinical research, standardized and valid measurement instruments are still lacking (121, 125, 132, 166). In 2014, Bowling et al. conducted a literature review of patients' expectation measurement tools in a variety of health care disciplines. This review included 213 studies conducted between 2000 and 2009. The authors concluded that there is no consensus on the definition of 'expectations' and most of the questionnaires used in studies were not validated or tested for reliability. In 2014, the Patients' Expectations Questionnaire (PEQ) was developed and validated by Bowling and Rowe (121). This 27-item questionnaire measures patients' expectations on six domains related to ambulatory health care: 1) structure of health care, 2) process of health care, 3) doctor-patient communication, 4) consultation and treatment or procedures performed, 5) doctor's approach to information, and 6) treatment outcomes (121).

In summary, in the field of dentistry the concept of patients' expectations and the related measurement scales are still not very well developed. The Visual Analogue Scales (VAS) is the instrument that has been most used to assess patients' expectations of treatment (107, 130, 132, 167). The VAS allows patients to rate their expectation with the prosthesis on a scale ranging

from 0 mm, to 100 mm (130) of different aspects of the prosthesis such as, stability, retention, comfort, aesthetics and chewing abilities.

CHAPTER 2: METHODOLOGY

2.1 PROBLEM, HYPOTHESIS, OBJECTIVES

The mandibular two-implant-assisted overdentures have been reported to be a successful and cost-effective treatment option (54, 168). However, individuals wearing two-implant-assisted mandibular overdentures with resilient stud attachments may perceive rotational movement of the denture base, which can decrease their ability to chew and their level of satisfaction with the overdenture (42, 61, 169). Adding a third midline implant to the two-implant overdenture can preclude rotational movement of the overdenture without resulting in higher strain on the denture-bearing mucosa, abutment, or implant (42, 62). Despite the increase use of the three-implant denture in dental practices with favorable reported clinical outcomes, evidence on the impact of the three-implant-assisted overdentures on patient-reported outcomes, especially with universal resilient attachments such as Locators, remains scarce (42, 59, 62). Thus, the overall goal of this master's project was to provide patient-reported data on the effectiveness of mandibular three-implant overdenture with Locator attachment. The primary research question was: Is there any difference in satisfaction (Primary outcome) of completely edentulous adults (population) when their mandibular two-implant-assisted overdenture (Comparison) is converted to three-unsplinted-implant-assisted overdenture (Intervention)?

2.1.1 Study objectives

1. Primary objective: To assess the impact of the conversion of the mandibular two-unsplinted-implant-assisted overdenture to three-unsplinted-implant-assisted overdenture on patient satisfaction at 6 weeks post intervention.

2. Secondary objectives:

a) To examine patients' expectations in regard to the mandibular three-unsplinted-IAO.

b) To investigate patients' willingness to pay for the differential cost of the mandibular three-unsplinted- IAO.

2.1.2 Study hypothesis

We tested the following null hypotheses:

There is no difference in the level of patients' satisfaction with the mandibular overdenture with two or three unsplinted implants after 6 weeks of chair-side conversion.

2.2 RESEARCH METHODS

2.2.1 Study design and study participants

This study presents the second phase of a previous clinical trial with a pre-test/post-test design, with the objective of evaluating the impact of immediate-loading protocol on patient-based outcomes (107, 153). The two study phases, Phases I and II, were conducted at the Oral Health

and Rehabilitation Research Unit at the Université de Montréal; and the ethical approval was granted by the Université de Montreal Ethical Review Board (certificate no. CERSS#990).

In Phase I of the study, via conventional (n = 1) or immediate loading (n = 19) protocols, each patient received three threaded implants (OsseoSpeed™, DENTSPLY Implants) in the interforaminal mandibular area and a mandibular two-implant-unsplinted overdenture, with Locator attachments (LOCATOR® abutment; ZEST Anchors L.L.C., Escondido, CA, USA) and a new set of conventional maxillary dentures. These patients were informed about the unloaded midline implant and the conversion of the prosthesis in Phase II of the study at 2-year follow-up.

2.2.2 Eligibility criteria and study intervention

Participants in Phase I of the study were considered for inclusion in Phase II if:

- They were willing to participate in Phase II and provided written informed consent.
- All of the three implants at 2-year follow-up were successful according to the implant success criteria as defined by Zarb and Albrektsson (170).
- They had the physical and psychological capacity to complete study questionnaires.

From a total of 21 patients who received three implants and a two-implant-assisted overdenture in Phase I of the trial, only 17 met the Phase II eligibility criteria as detailed in Fig. 3.1. All of these individuals accepted to participate in the Phase II and signed an informed consent.

The study intervention consisted of the conversion of the mandibular two-unsplinted-implant to three-unsplinted-implant-assisted overdenture by adding a Locator abutment (ZEST Anchors L.L.C., Escondido, CA, USA) to the midline implant with a torque of 35 Ncm following standard chair-side procedure. The intervention was conducted by an academic prosthodontist, at the Oral Health and Rehabilitation Research Unit at the Université de Montréal. All patients were followed over a 6-week period.

2.2.3 Data collection and outcome measures

Data collection was conducted before the intervention (T0) and at 6-week post-intervention (T1). The primary study outcome was patients' satisfaction with the mandibular implant-assisted overdenture, which was measured using the adapted McGill denture satisfaction questionnaire (107, 110, 152, 153). The secondary outcomes of interests were patients' expectations of the conversion of their 2-implant overdenture to 3-implant and patients' willingness to pay the cost of the conversion. Patients 's expectation in regard to satisfaction with overdenture, its stability, retention and comfort, and the ability to chew was measured was measured using a 100-mm visual analog (VAS) (107) and binary scales respectively.

The patients' willingness to pay the cost of the conversion and the impact of mode of payment on their decision-making were assessed using binary items and an open-ended question (171-174). Finally the patients were asked if they would recommend the three-implant overdenture to

their peers.

The explanatory variables included the perceived anterior–posterior movement of the overdenture and socio-demographic characteristics. The perceived anterior–posterior movement of the prosthesis was measured with binary scales. Additionally, evaluation of the clinical anterior–posterior movement was accomplished using the Functional Denture Assessment scale (175, 176). Self-administered questionnaire was used to capture socio-demographic characteristics of the study participants. .

2.2.4 Power calculation and statistical analysis

Based on a Wilcoxon signed rank test, assuming that (i) the minimal clinically important pre–post difference in the mean global satisfaction score is 25 units (8, 102, 109, 177-179) and (143) the standard deviation of the distribution of the global satisfaction score is 34 units (109), a sample size of 17 participants will insure a power of 80% for rejecting the null hypothesis if it is indeed false, at an alpha level of 5%.

Descriptive statistics were used to examine the measures of central tendency and variability in the study sample.

Patients' satisfaction with the prosthesis and its dimension change scores were computed as follows: $\Delta = T_1 - T_0$. Wilcoxon's signed-rank test was used to test the statistically significance difference between the pre and post satisfaction scores. Spearman's correlation and Mann-

Whitney U test were used to assess the association between patients' satisfaction and socio-demographic variables as well as the post-intervention perceived and clinical anterior–posterior movement.

To determine whether the patients' expectations in regard to three-implant-assisted overdenture had been met, the difference between the scores of expected satisfaction and post-intervention satisfaction was calculated. Zero or positive values represented met expectations (107, 180).

McNemar's test was used to compare the pre–post perceived and clinical anterior–posterior rotational movement scores as well as the pre–post willingness to pay (WTP) binary scores.

The association between the socio-demographic variables, the patients' satisfaction change scores as well as the mode of payment (monthly installment) with the post-intervention WTP values was examined using Spearman's rank correlation, Mann-Whitney U test, and Fisher's exact test, depending on the nature of data (continuous or dichotomous). Multicollinearity was examined based on Tolerance and Variance Inflation Factor.

The level of significance was set at $p \leq .05$. Data analyses were performed using SPSS 21.0 (SPSS Inc., Chicago, IL, USA) and the SAS program (SAS 9.4 for Windows, Cary, USA).

2.3 STUDY RELEVANCE

To our knowledge, this study is the first clinical trial that sheds light on the conversion of two-unsplinted-implant-assisted overdenture to three-unsplinted-implant-assisted overdenture

regarding patient-based outcomes. The findings of this research will provide scientific evidence that leads to a better understanding of patients' expectations and perspective in regard to three-implant overdenture. Additionally, this research project will provide information that helps clinicians and patients in the process of decision-making for the choice of mandibular prosthesis.

2.4 CANDIDATE'S ROLE IN THE PROJECT AND KNOWLEDGE TRANSFER ACTIVITIES

The candidate was responsible for data management and data analysis. She also participated actively in the knowledge-transfer phase of this research project.

The candidate presented the results of this research project during several scientific meetings and conferences.

1) Oral presentations:

- Two- versus three-implant-assisted mandibular overdenture: Patients' satisfaction and expectation. Séminaires en sciences buccodentaires, Faculté de médecine dentaire, Université de Montréal, 2017.
- The keys to success and winning international awards. Faculté de médecine dentaire, Université de Montréal, 2017.

2) **Poster presentations:**

- A. Alesawy, D. Cerutti-Kopplin, N. Kodama, R. Durand, P. Rompré, P. de Grandmont, E. Emami. Two- versus three-implant-assisted mandibular overdenture: Patient-based outcomes. J Dent Res 96 (Spec Iss A): #2638380, 2017. IADR Prosthodontic Research Group, **Recipient of Neal Garrett prize**.
- A. Alesawy, D. Cerutti-Kopplin, N. Kodama, R. Durand, P. Rompré, P. de Grandmont, E. Emami. Two- versus three-implant-assisted mandibular overdenture: Patient-based outcomes. Journée scientifique de l'Université de Montréal, Montréal, Canada, 2017.

Chapter 3 of the current master research project will be also submitted for publication in a journal in the field of implantology.

CHAPTER 3: RESULTS

3.1 MANUSCRIPT

A within-subject clinical trial on the conversion of mandibular 2-implant- to 3-implant-assisted overdenture: Patient-centered outcomes

Key words: Clinical trial, Dental implants, Overdentures, Mandibular prosthesis, Patient satisfaction.

A within-subject clinical trial on the conversion of mandibular 2-implant- to 3-implant-assisted overdenture: Patient-centered outcomes

ABSTRACT

Objectives: To examine the impact of adding a third midline implant with stud attachment to a mandibular 2-unsplinted-implant overdenture on patient-oriented outcomes (patients' satisfaction and expectations).

Methods: In this pre–post design clinical trial, following the standard procedures, mandibular 2-unsplinted-implant-assisted overdentures of 17 edentate individuals (61.9 ± 6.6 years) were converted to 3-implant overdentures by adding a third Locator™ attachment (Zest Anchors LLC, Escondido, CA, USA) to an unloaded midline implant. Patient-oriented outcomes included patient expectations and satisfaction with implant overdenture as well as willingness to pay the cost of conversion. Data were collected at baseline and at the 6-week follow-up using visual analog and binary scales as well as open-ended questions. Statistical analysis included descriptive statistics, Spearman's correlation, Fisher exact test, Mann-Whitney U, and Wilcoxon signed-rank test.

Results: After connecting the third midline implant to the 2-unsplinted-implant mandibular overdenture, there was a statistically significant decrease in the anterior–posterior movement (p

= 0.005) as evaluated by clinicians. Moreover, study participants reported an increase in perceived stability of the overdenture ($p = 0.005$), and in their ability to speak ($p = 0.011$) and to chew hard food ($p = 0.012$). The addition of a third implant met the expectations of 94% of patients in regard to lower denture stability, 100% for retention, and 82.4% for comfort. The 3-implant-assisted mandibular overdenture increased patient general satisfaction over a short period of time, but this improvement was not statistically significant. About 80% of patients would recommend this type of prosthesis to their peers but only 47% of them would agree to pay a large increase in the cost of treatment compared to a 2-implant-unsplinted-assisted overdenture.

Conclusions: The addition of a midline third implant to an existing 2-mandibular-implant overdenture leads to better patient-based outcomes. However, the additional cost of the treatment may influence patient preferences.

INTRODUCTION

A variety of removable implant-assisted prostheses exist to restore the functionality of completely edentate individuals (181). The treatment of fully edentulous mandible using implant overdenture anchored to two unsplinted implants has been shown to be considerably cost-effective, with predictable long-term outcomes (2-5). Stud attachments such as Ball or Locator™ attachments have been widely used as implant supra-structure for this type of prosthesis, mostly because of their affordability for the patient and the simplicity of the treatment for the clinician (6-8). Since the success and survival rate of mandibular implant overdentures are not associated with the type of overdenture attachment system (9-12), patient satisfaction with implant overdentures will mainly depend on how well the prosthesis restores their oral function and the complications that they may have with the prosthesis over time. The results of a randomized clinical trial with 8-year follow-up showed that patients wearing mandibular implant-assisted overdenture with stud attachments were less satisfied with the retention and stability of their overdenture than those having splinted implants via a bar as superstructure (13). Furthermore, it has been reported that individuals wearing a 2-implant overdenture with resilient stud attachments perceived a rotational movement of the denture base around the attachments, which can reduce their ability to chew hard food as well as their satisfaction with the overdenture (14-17).

The addition of a midline abutment to a mandibular 2-implant overdenture has been suggested as a strategy to decrease the rotational movement of these prostheses without increasing the strain on the denture-bearing mucosa, abutment, or implant (16, 17). The 3-dimensional finite element analysis conducted by Liu et al. (181) demonstrated that vertical loading of the mandibular 2-implant-assisted overdenture with Locator™ attachments causes more rotational movement and higher stress in the abutments than the 3-implant overdenture. Furthermore, no damaging strain concentration was observed in the peri-implant bone of the midline implants.

Mandibular 3-implant overdentures have been previously used in the rehabilitation of edentulous mandible (17). Favorable clinical outcomes such as high implant survival and success rates have been documented for 3-implant overdentures with freestanding attachments (10, 14, 18, 19). The results of a long-term prospective study of 95 edentate patients demonstrated that 3-implant mandibular overdentures have a survival rate similar to 4-implant overdentures (181). Moreover, the results of a quasi-experimental study published by Emami et al. (17) in 2014 showed that from a total of 135 patients wearing mandibular 3-implant overdentures, only 18.5% of patients reported having rocking movement and more than 75.6% of the total were completely satisfied with this type of prosthesis. In this study, rotational movement explained 15% of the change in the oral health-related quality of life.

However, there is still a scarcity of patient-centered data in regard to 3-implant overdenture,

especially those with unsplinted attachments (10, 16, 17). Thus, the overall goal of this study was to provide such data, and its specific objective was to examine the impact of adding a third midline implant to a mandibular 2-unsplinted-implant overdenture using Locator™ attachments, on patient-oriented outcomes. The primary study outcome was patient satisfaction and we tested the null hypothesis that there is no difference in patient general satisfaction between the two types of mandibular implant-assisted overdenture (2- versus 3-implant-assisted overdenture).

MATERIALS AND METHODS

Trial Design

This manuscript follows the CONSORT guidelines to report the trial results. The trial was designed as a pre–post clinical trial in two phases. During Phase I, 21 edentate elders received three threaded implants (OsseoSpeed™, DENTSPLY Implants, Mölndal, Sweden) in the interforaminal mandibular area, and underwent oral rehabilitation with a new maxillary prosthesis and a 2-implant mandibular overdenture via conventional (n = 2) or immediate loading (n = 19) protocol following prosthodontics standard guidelines. The details and results of Phase I of this trial have been previously published (21, 22). All study participants were informed about Phase II of the trial and the loading of the midline implant at the 2-year follow-up.

The eligibility criteria for Phase II of the trial included:

1) Willingness to participate in Phase II; 2) success of the 3 implants at the 2-year follow-up as defined by Zarb and Albrektsson's criteria (23); 3) having the physical and psychological capacity to complete the study questionnaires.

As shown in the study flowchart (Fig. 3.1), from a total of 21 individuals who received 3 implants during Phase I of the trial, only 17 (mean age = 61.9 ± 6.6 years) met the Phase II eligibility criteria. All eligible individuals accepted to participate in Phase II and signed an informed consent. Ethical approval for Phase II was obtained from the Université de Montréal Health Research Ethics Committee.

Study Intervention

The study intervention consisted of the conversion of the 2-implant to a 3-implant mandibular overdenture. The intervention was conducted by an academic prosthodontist at the Oral Health and Rehabilitation Research Unit at the Université de Montréal. To avoid any potential measurement bias in the trial, before the intervention, all the mandibular overdenture Locator Males were replaced by new ones (Extended Range Males, green option with retention force of 4 lbs.) and the overdentures were relined and adjusted. Patients were followed 2 times over a 2-week period to ensure their comfort with the prosthesis. At the 2-week follow-up, the

overdenture conversion was conducted by adding a Locator™ abutment (ZEST Anchors L.L.C., Escondido, CA, USA) to the midline implant following standard chair-side procedures.

Outcome Measures and Data Collection

Data collection was conducted before the intervention (T0) and at 6 weeks post-intervention (T1). The primary study outcome was patient satisfaction with the mandibular implant-assisted overdenture, which was measured using the adapted McGill denture satisfaction questionnaire (21, 24, 25). The secondary outcomes of interests were patients' expectations of the conversion of their 2-implant overdenture to 3-implant, and patients' willingness to pay the cost of the conversion. Patients' expectations in regard to satisfaction with overdenture, as well as its stability, retention, and chewing ability were measured using a 100-mm visual analog scale (VAS) (21) and binary scales, respectively.

The patients' willingness to pay an additional cost of minimum $2,000 for the conversion of implant mandibular overdenture, the maximum amount of money that they were willing to pay for the conversion of their overdenture, their preferred choice if the cost of 2- and 3-implant overdenture was similar, as well as the impact of mode of payment on their treatment decision were assessed using items with dichotomous response (yes/no) and open-ended questions (27). Finally, the patients were asked if they would recommend the 3-implant overdenture to their peers.

The explanatory variables included socio-demographic characteristics and the rotational movement of the overdenture before and after the overdenture conversion. The latter was assessed clinically by the use of the Functional Denture Assessment scale (26, 27) and from patients' response to a binary item in this regard. A self-administered questionnaire was used to capture participants' socio-demographic characteristics.

Sample Size

Based on a Wilcoxon signed-rank test, assuming that (i) the minimal clinically important pre–post difference in the mean global satisfaction score is 25 units (28-33) and (143) the standard deviation of the distribution of the global satisfaction score is 34 units (28), a sample size of 17 participants will insure a power of 80% for rejecting the null hypothesis, if it is indeed false, at an alpha level of 5%.

Statistical Analyses

Descriptive statistics were performed to examine the measures of central tendency and variability in the study sample. Wilcoxon's signed-rank test (non-parametric test for two related samples) was used to examine whether there was a difference in patients' satisfaction and its dimensions before and after 6 weeks of conversion of the implant overdenture. Spearman's correlation,

Fisher's exact test, and Mann-Whitney U test were used to assess the association of patients' satisfaction with socio-demographic variables as well as the post-perceived and clinical anterior–posterior rotational movement scores.

The VAS scores of patients' expectations of their general satisfaction with 3-implant–assisted overdenture were considered high if VAS $\geq$ 90. To determine whether their expectations had been met, the difference between the scores of expected satisfaction and post-intervention satisfaction was calculated. Zero or positive values represented met expectations (21, 34).

McNemar's test was used to compare the pre–post perceived and clinical anterior–posterior rotational movement scores as well as the pre–post willingness to pay (WTP) binary scores. The association between the socio-demographic variables, the patients' satisfaction change scores (T_1-T_0) as well as the mode of payment (monthly installment) binary scores with the post-intervention WTP values were examined using Spearman's rank correlation, Mann-Whitney U test, and Fisher's exact test, depending on the nature of data (continuous or dichotomous). The level of significance was set at $p \leq .05$. Data analyses were performed using SPSS 21.0 (IBM Co., Armonk, NY, USA) and SAS 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

The socio-demographic characteristics are presented in Table 3.1.

Before the intervention, the majority of the study participants (88.2 %) had high satisfaction expectation of the conversion of their 2-implant-assisted mandibular prosthesis to 3-implant overdenture, and all of them expected that the 3-implant-assisted overdentures would positively influence the stability and retention of their overdenture as well as their ability to chew with it. The overdenture conversion had met the satisfaction expectations of 70.7% of the participants and 88.2% percent of them were highly satisfied with this treatment.

The majority of study participants agreed that the addition of the third implant had positively influenced their chewing ability (88%), their comfort (82.4%), and the retention (100%) and stability (94%) of their mandibular prosthesis.

Table 3.2 presents participants' satisfaction score change, mean change, and the range of scores at the 6-week follow-up.

As presented in Table 3.3, the Wilcoxon's signed-ranks test showed a statistically significant difference between pre- and post-intervention scores in denture stability ($p = 0.005$), ability to chew hard food ($p = 0.012$), and ability to speak ($p = 0.011$). The addition of the third midline Locator™ to the 2-implant overdenture did not affect its ease in removal and insertion ($p > 0.5$).

Although the pre-intervention clinical assessment revealed a pronounced anterior–posterior movement in the overdenture in the majority of the patients ($n = 16$), only 35% of them ($n = 6$) had perceived this movement. After the conversion, rotational movement was still perceived in

four participants. However, it had decreased in 49% of patients according to the clinical assessment (n = 9). The pre–post difference in the rotational movement scores was statistically significant only within the clinical assessment ($p = 0.005$).

There was no association between the socio-demographic variables and perceived and clinical anterior–posterior movement post-scores, and patients' satisfaction post-scores ($p > 0.05$).

At baseline, 30% of participants were willing to pay an extra cost of $2,000 for the conversion of their overdenture to 3-implant mandibular overdenture. Post-intervention this percentage had increased to 47%. The pre–post difference in willingness to pay the extra cost was not statistically significant ($p = 0.25$). At baseline, the range (max–min) of maximum amount of money that patients would pay for conversion of their mandibular implant overdenture was $1,250. After the intervention, the range increased to $1,500. Ninety-four percent (94%) of patients would have chosen the 3-implant mandibular overdenture, if the cost was similar to that of a 2-implant overdenture.

The associations between age, income, education, and patients' satisfaction score change as well as mode of payment with post-intervention WTP dichotomous data were not statistically significant ($p > 0.05$). However, compared to men, women were more willing to pay an extra cost of $2,000 for a 3-implant overdenture ($p = 0.03$). Finally, 80% of the study participants would recommend the mandibular 3-unsplinted-implant-assisted overdenture to their peers.

DISCUSSION

This clinical trial investigated the impact of the conversion of 2-unsplinted-implant overdenture to 3-implant overdenture on patient-oriented outcomes. The study findings showed that this treatment met the expectations of the majority of patients and increased their satisfaction with stability of the implant-assisted overdenture. However, the findings showed that patient decision-making to pay for 3-implant overdenture would depend on the cost of the treatment and not on their satisfaction or preference for this treatment.

To our knowledge, this is the first clinical trial investigating patients' expectations and satisfaction in regard to the conversion of a 2- to 3-implant-assisted mandibular overdenture with unsplinted supra-structure (21, 35). These two outcomes are important and relevant for any clinical discipline, since an understanding of the nature of patients' expectations and satisfaction enables clinicians to address patients' perspectives and needs (21, 35, 36). Moreover, patient satisfaction is an indicator of the quality of care (37).

Previous research on the expectations of edentulous patients in regard to mandibular implant overdenture has shown that patients are more satisfied if their expectations are met (21, 38). High patient expectations can lead to underestimation and concerns about the treatment and its magnitude of effect. This can be easily handled by an effective communication between the clinician and the patient prior to treatment (39, 40).

In this trial, the majority of patients had high expectations of the conversion of their overdenture to a 3-implant-assisted overdenture in terms of increased stability, retention, and their ability to chew. These expectations were reflected in patients' satisfaction domains since among various dimensions of patient satisfaction, stability and the ability to chew reached a statistical significance level. These results can be explained by a decrease in the rotational movement of the overdenture due to tripod support that can act as an indirect retainer (14, 16, 41). This explanation is in line with the results of a recent *in vitro* study by Oda et al. (42) suggesting that the 2-implant overdenture mainly dislodges in a vertical direction upon anterior loading, and that adding a midline implant inhibits the hinge movement and decreases the posterior upward movement of the denture base. Findings of a study by Kimoto et al. (15) indicate that rotational movement is greatly influenced by the anterior positioning of anterior teeth. The within-subject analysis and the conversion of existing overdenture allowed us to compare this movement in 2 versus 3 implants, regardless of this contributing factor.

However, in the present study, although the decrease in anterior–posterior movement of the overdenture after the conversion was statistically significant in expert-based assessment, it was non-significant from patients' perspectives. Furthermore, the post-intervention assessment of rocking movement was not correlated with patient satisfaction post-scores. In fact, in this trial only 35% of patients reported a rocking movement with their mandibular 2-implant-assisted

overdenture. This percentage is quite similar to those reported in the study conducted by Kimoto et al. (15) and confirms previous findings that patient's self-assessment and expert-based assessment are poorly correlated (24, 43-48). Since self-assessment can be less sensitive to change and can be biased by patients' expectations of improvement, the use of both objective and subjective measures can be helpful to better analyze and explain the data.

Our findings are in line with previous retrospective clinical studies in regard to high satisfaction rate among patients wearing a 3-implant-assisted overdenture with ball or bar attachments (10, 17). Additionally, our study showed that the conversion of 2-implant-assisted to 3-implant-assisted overdenture might increase the satisfaction with speech and chewing hard foods, which may be related to the enhanced stability of the overdenture. Importantly, this conversion did not influence the ease of cleaning, removal, and insertion of the prosthesis, which are essential factors for patients, specifically elders with physical disabilities and reduced dexterity.

Despite these advantages, not all of the study participants were willing to pay the cost of this treatment. Willingness to pay, or WTP, has been defined by Hanley et al. (49) as the maximum price that a patient would be willing to pay for a health service. WTP is a valuable outcome in clinical practice, complementing other patient-reported outcomes by adding the value that patients would agree to pay to gain a benefit from a treatment. Several factors such as patient's age, sex, income, and monthly installments have been reported to influence WTP for implant

treatment (50-53). However, our study found only a sex difference for WTP. This could be explained by the theory of planned behavior and women having higher health consciousness than men (54). On the other hand, we can assume from patient experiences of the overdenture conversion in our study, that the choice and preference for the 3-implant-assisted overdenture is conditional on similar cost to that of the 2-implant-assisted overdenture. Feine et al. (181), in a study on choice of mandibular implant-assisted overdenture, reported that both cognitive and affective factors influence the choice of prosthesis in edentulous patients. Our results favor cognitive (reasoning) aspects and acknowledge the cost-effectiveness of the 2-implant-assisted mandibular overdenture, as previously stated in McGill and York (5, 56). However, these results cannot be generalized to other populations such as those individuals having a dentate maxilla that would result in a different pattern of occlusal force, which may induce more anterior vertical load to the mandibular prosthesis.

The non-statistically significant differences in patients' general satisfaction and comfort as well as the lack of association between WTP and other socio-economic characteristics might be attributable to the fact the study participants were very satisfied with their 2-implant overdenture, which was provided by an experienced prosthodontist.

On the other hand, the variation in WTP values is not always explainable (57-59). Several factors could be associated to patients' evaluation of the treatment, and their WTP might be influenced

by their real needs rather than the level of satisfaction with their actual oral health status (50, 51). Some limitations should be highlighted and considered for the interpretation of the results of this trial. Firstly, methodological issues with single-group quasi-experimental pre–post design should be acknowledged, including the lack of control group and potential for response shift bias (181). Furthermore, a short-term follow-up period did not allow evaluation of long-term patient satisfaction with this treatment, which may be influenced by factors such as hygiene, peri-implantitis, retention loss, and complications with Locator™ attachments. El-Sheikh et al. (181) compared clinical outcomes and maintenance of 2- versus 3-narrow-implant mandibular overdenture with Locator™ attachments in 20 edentate patients aged 54–68 years old. Their 2-year follow-up showed no between-group differences in peri-implant tissues, bone loss, and prosthetic complications.

Using a within-subject pre–post design with short-term outcomes has some advantages in terms of controlling the source of memory bias, patients' variation, and the study budget. It should be noted that Phase II clinical trials, while being a good source for evidence-based practice among other benefits (62), are necessary to guide the conduct of Phase III clinical trials involving many patients in a large randomized trial.

CONCLUSION

The conversion of a 2-unsplinted-implant-assisted mandibular overdenture to a 3-implant-assisted overdenture could improve patients' satisfaction in regard to the stability of the prosthesis. However, the preference for 3-implant and WTP for this modality of treatment depend on the additional cost.

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List of Figures and Tables

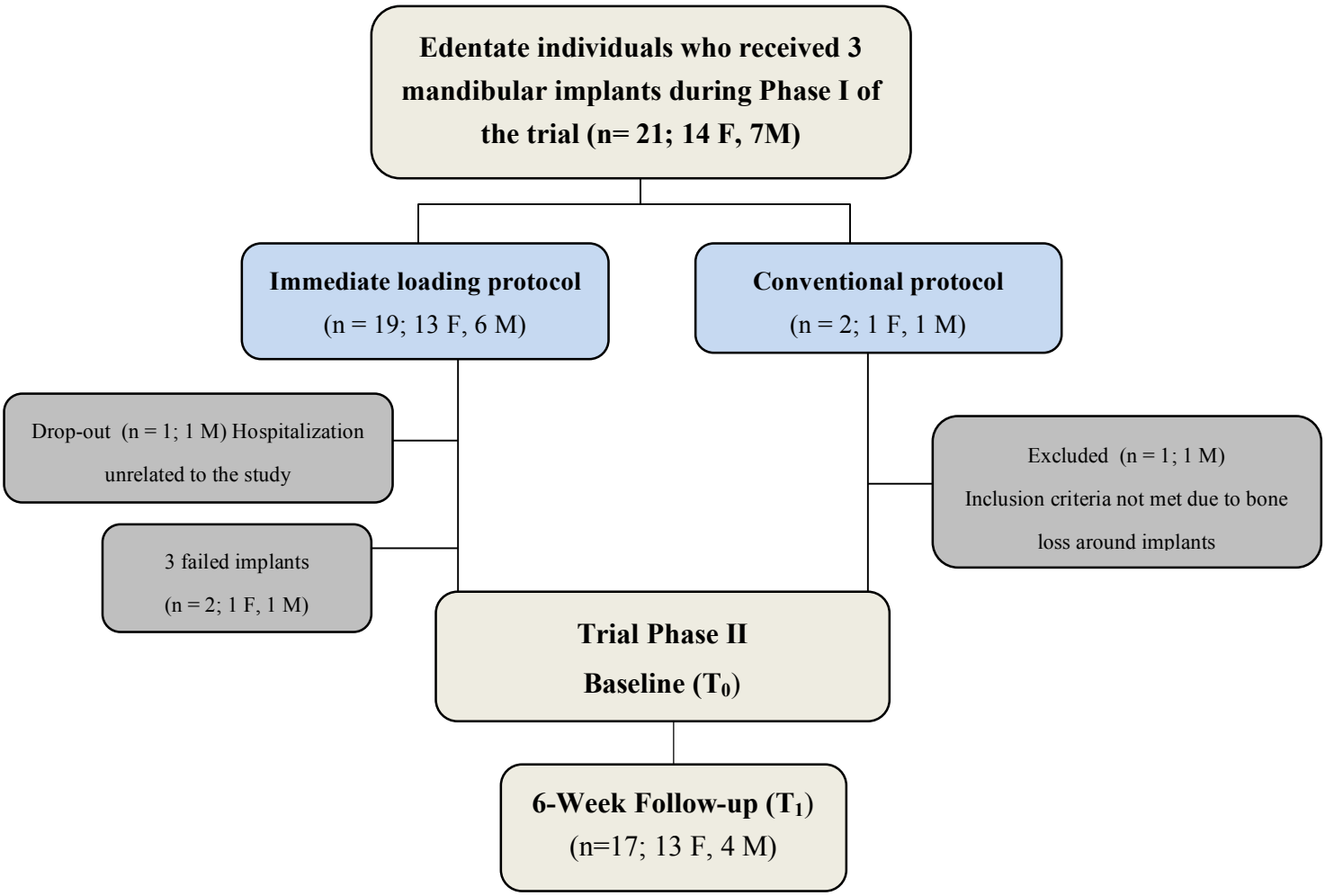

Figure 3.1: Study flow chart

Table 3.1: Participants' socio-demographic characteristics (n=17)

Mean age (Years ± SD)	61.9 ± 6.6
Gender (%)	
Males	29.4%
Females	70.6%
Marital status (%)	
Single/Separated/Divorced	35.6%
Married/Partnered	57.9%
No response	5.9%
Living status (%)	
Alone	5.9%
With family/Others	70.8%
No response	23.5%
Education (%)	
Elementary/High school	58.8%
College/University	41.1%
Income (%)	
< $40,000	41.2%
≥ $40,000	47.0%

Table 3.2: Patients' satisfaction score change (T_1-T_0) with the 3-implant-assisted overdenture after 6 weeks (n = 17)

Participant	General satisfaction	Ease of cleaning	Ability to speak	Comfort	Esthetics	Stability	Ability to chew hard food	Ease of removing	Ease of insertion	Function	Oral condition
1	0	2	0	0	0	0	0	42	0	1	0
2	– 1	0	1	0	0	1	9	– 2	– 2	–2	0
3	11	0	0	0	0	16	12	0	0	0	0
4	0	0	0	0	0	0	0	0	10	0	0
5	0	0	0	0	0	0	0	– 10	– 10	0	0
6	5	–20	0	0	0	21	0	0	– 10	–15	0
7	5	0	6	3	3	16	29	2	21	3	–1
8	54	0	2	51	0	82	55	0	– 1	9	52
9	0	0	0	0	0	0	0	0	– 14	0	0
10	0	1	1	0	1	14	0	0	0	0	0
11	2	–1	3	1	3	2	8	1	3	2	0
12	– 6	0	0	0	0	0	0	0	4	0	0
13	26	1	6	17	0	6	6	0	– 15	45	17
14	0	0	0	11	0	8	7	– 5	– 14	0	0
15	– 9	0	6	–6	8	5	7	0	– 94	4	–4
16	0	0	0	–6	0	0	–5	8	9	0	12
17	0	3	1	0	0	0	–4	0	0	0	0
Mean change	**5.1**	**– 0.8**	**1.5**	**4.2**	**0.9**	**10.1**	**7.3**	**2.1**	**– 6.6**	**2.8**	**4.5**
Min-Max	**–9 to 54**	**–20 to 3**	**0 to 6**	**–6 to 51**	**0 to 8**	**0 to 82**	**–5 to 55**	**–10 to 42**	**–94 to 21**	**–15 to 45**	**–4 to 52**

	N	Mean Rank	Sum of ranks	Wilcoxon's Signed Ranks test	
				Z-scores	P-value
General satisfaction				– 1.2	0.213
Negative ranks*	3	4	12		
Positive ranks**	6	5.5	33		
Ties***	8				
Ease of cleaning				–0.5	0.596
Negative ranks*	2	4	8		
Positive ranks**	4	3.23	13		
Ties***	11				
Ability to speak				–2.5	**0.011**
Negative ranks*	0	0	0		
Positive ranks**	8	4.5	36		
Ties***	9				
Comfort				–1.2	0.236
Negative ranks*	2	3.5	7		
Positive ranks**	5	4.20	21		
Ties***	10				
Esthetics				–1.8	0.066
Negative ranks*	0	0	0		
Positive ranks**	4	2.5	10		
Ties***	13				
Stability				–2.8	**0.005**
Negative ranks*	0	0	0		
Positive ranks**	10	5.5	55.5		
Ties***	7				
Ability to chew hard food				–2.5	**0.012**
Negative ranks*	2	1.5	3		
Positive ranks**	8	6.5	52		
Ties***	7				
Ease of removing				–0.3	0.799
Negative ranks*	3	4.17	12.5		
Positive ranks**	4	3.88	15.5		
Ties***	10				
Ease of insertion				–1.0	0.310
Negative ranks*	8	7.5	60		
Positive ranks**	5	6.20	31		
Ties***	4				
Oral function				–1.2	0.233
Negative ranks*	2	4.75	9.5		
Positive ranks**	6	4.42	26.5		
Ties***	9				
Oral condition				–1.2	0.225
Negative ranks*	2	1.5	3		
Positive ranks**	3	4	12		
Ties***	12				

*Negative Ranks: Post-Intervention VAS < Pre-Intervention VAS
**Positive Ranks: Post-Intervention VAS > Pre-Intervention VAS
***Ties: Post-Intervention VAS = Pre-Intervention VAS

Table 3.3: Ranks comparisons within patient satisfaction domain (n = 17)

CHAPTER 4: DISCUSSION

The goals of this master's research project were:

1. To assess the impact of the conversion of the mandibular two-unsplinted-implant-assisted overdenture to three-unsplinted-implant-assisted overdenture on patient satisfaction at 6 weeks post intervention.
2. To examine patients' expectations in regard to the mandibular three-unsplinted-implant-assisted overdenture.
3. To investigate patients' willingness to pay for the differential cost of the mandibular three-unsplinted-implant-assisted overdenture.

The results of this research project demonstrated that the conversion of the mandibular *two*-unsplinted-implant overdenture to three-unsplinted-implant-assisted overdenture met the expectations of the majority of study participants in regard to mandibular overdenture stability, retention, and comfort. The majority of the study participants reported being satisfied with the perceived stability of their overdenture, and with their ability to speak and to chew hard food after the conversion. About 80% of study participants have recommended three-unsplinted-implant-assisted overdenture to their peers but about half of them have agreed to pay the additional cost compared to two-implant-assisted overdenture. Patients' willingness to

pay for this prosthetic treatment was dependent on its cost rather than the benefit brought by the treatment.

4.1 PATIENTS' PERSPECTIVES REGARDING MANDIBULAR THREE-IMPLANT-ASSISTED OVERDENTURES: EXPECTATIONS AND SATISFACTION

The effectiveness of any medical treatment has two main dimensions: improvement of signs and symptoms and patient perception of treatment results (96). Incorporating patient-reported outcomes in addition to the clinical outcomes in the assessment of cost-effectiveness of any treatment will better inform practice and thereby improve the quality of patients' health care (95-97, 182, 183).

In this research project, three patient-reported outcomes were selected: patient's expectations, satisfaction, and willingness to pay. To our knowledge, this is the first clinical trial to provide comprehensive patient-reported evidence regarding the conversion of the two- to three-implant-assisted mandibular overdenture. The majority of previous studies have reported disease-reported outcomes in regard to three-implant-assisted overdentures (18, 49, 184, 185). As discussed below, we have only found two studies in the literature with which we are able to compare our results (59, 62).

4.1.1 Patients' expectations of mandibular three-implant-assisted overdentures

From the clinical perspective, it is extremely important to understand and manage patients' expectations prior to treatment. This knowledge and pre-management may help clinicians to maximize patients' satisfaction with the treatment received (132, 186).

The results of this research project show that the majority of patients wearing, for a period of 2 years, a two-implant-assisted overdenture with stud attachments had high expectations (97 mm on 100 mm VAS scale) regarding the impact of the conversion of their overdenture to three-implant in regard to improving the stability, retention, and comfort of their overdenture. Our findings are comparable to the findings of research conducted by Heydecke et al. (167) on patients' expectations regarding mandibular 2-implant-assisted overdenture with two stud attachments. In that study of individuals ranging from 35 to 75 years old, patients had an expectation rating of about 90 mm on a 100 mm VAS scale, regardless of age.

According to the literature, expectation appears to be influenced by various factors including experience with previous treatment (187), personality traits and individuals' characteristics (107, 188), individuals' beliefs (189, 190), media-awareness of various treatments (191, 192), as well as patient–clinician communication (192).

In our study, the high expectation regarding the conversion of two- to three-implant-assisted

overdenture can be explained by the information that the patients received in phase I of this study regarding the conversion and its possible impacts on overdenture stability. Although more than 80% of the patients were highly satisfied with their mandibular overdenture after the conversion, we didn't find a statistically significant correlation between patient expectation and general satisfaction ($r = -0.027$, $p = 0.9$). This is different from Heydecke et al's findings regarding patients' expectation toward mandibular two-implant-assisted overdenture with stud attachments with stud attachments (167). In their study, a weak but statistically significant correlation was found between patient satisfaction and expectation ($r = 0.26$, $p = 0.009$), and about 40% of variance in patients' satisfaction scores were explained by the expectation scores.

The correlation between patient satisfaction and expectation has been assessed in some studies (106, 130, 131) and a great variability has been reported among them. In fact, there is a controversy in the literature on how patients' expectations and satisfaction with treatment outcomes are correlated (126, 193, 194). Some research has shown that they are associated in a linear manner (107, 130, 131) while others found that expectations do not correlate with satisfaction (126, 193). The variation among the results could be due to inconsistency in the definition of expectation and in measures used, to the lack of a conceptual framework in the majority of clinical trials, as well as to differences in patients' characteristics and in types of treatment (106).

4.1.2 Patients' general satisfaction with mandibular three-implant-assisted overdentures with locator attachments

The findings of the present study show that the conversion of the implant-assisted overdenture from two to three implants increased patients' general satisfaction over a short period of time, and a statistically significant pre–post conversion difference was found in perceived satisfaction with denture stability, ability to chew hard food, and ability to speak. These findings are in line with the two previous clinical studies that have examined completely edentulous patients' satisfaction with three-implant-assisted removable prosthesis (59, 62). These results also confirm the findings of previous studies that indicated an improvement in overdenture stability would lead to better chewing ability (195, 196), and facilitate patients' ability to speak (186).

The first study that investigated patients' satisfaction with three-implant assisted overdenture was a practice-based study conducted by Emami et al. (62) in Montreal, Canada. In that study, 135 edentate elders rated their satisfaction with mandibular three-implant-assisted overdentures anchored by ball or locator attachments. Study results showed that 93.4% of the patients were totally or very satisfied with the mandibular three-implant-assisted overdenture, regardless of the type of attachment. This percentage was similar to our study, as all of our study participants were highly satisfied (VAS scores ≥ 90). However, we were not able to compare the results in depth since the Emami et al. (62) study was a post-treatment survey and thus did not have baseline

data to measure the magnitude of the improvement. Furthermore, in Emami et al. (62), patients had a conventional denture before receiving an implant-assisted overdenture, whereas in our study the patients had been rehabilitated with a mandibular two-implant-assisted overdenture.

The second clinical study was conducted by Geckili et al. (59) in 2011, at Istanbul University in Turkey. In this retrospective study, 23 patients who had worn a mandibular three-implant-assisted overdenture for at least 3 years were examined in regard to their overdenture satisfaction. Although the study has some methodological limitations including lack of baseline data, the results demonstrate that patients were very satisfied with three-implant overdentures regardless of the attachment type. However, Geckili et al. (59) did not assess patients' general satisfaction regarding the implant overdenture, and their study only examined the sub-domains of satisfaction (satisfaction with ability to speak, ease of hygiene, chewing ability, and comfort).

Our results are in line with those of Geckili et al. (59) in terms of high satisfaction of patients in regard to ability to speak, chewing ability, as well as comfort with the three-unsplinted-implant-assisted overdenture. However, we noticed a difference in the ratings of ease of cleaning between these two studies. The patients in our study had a higher rating in comparison to Geckili et al. (59)(98 mm versus 63 mm on VAS scale). This difference could be related to the type of attachment. In Geckili et al. (59), the implant overdentures were supported by bar or ball attachment, whereas in our study the Locators[73]were the only prosthetic components.

Individual attachments have been reported to be easier to clean than bars (12, 65, 197). According to a 3.5-year clinical study conducted by Cakarer et al. (198), which evaluated the prosthetic complications associated with the three different attachment systems (ball, bar, and Locator) in a sample of 36 completely edentulous patients (mean age 66.3 years), the Locator attachment system showed superior clinical results in terms of prosthetic complications such as hygiene problems and mucosal enlargement. The narrow space between bar attachment and mucosa (12), as well as the gradual loss of retention with ball attachments O-rings (198) could be the reasons for the difference.

Oral hygiene maintenance may also be influenced by patients' age (199), education level (200, 201), hygienic instructions received from clinicians (199, 202, 203), the length of the study follow-up, as well as the periodic check-up visits (203). Continuous wear of implant-assisted overdenture without periodic check-up visits may lead to attachments wear and retention loss (86), and thus more plaque retention and oral hygiene problems. However, Geckili et al. (59) did not report any data in regard to patient characteristics, which limited further exploration in this regard.

In our study, there was no significant difference in patients' ratings for ease of cleaning between two- and three-implant-assisted overdentures. These findings support the clinical study of El-Sheikh et al. (49), which followed 2074edentulous patients (mean age 60.4 years) for a

period of 24 months to compare the mean scores for indices of plaque, calculus, and bleeding with two and three narrow-diameter implant-assisted overdentures with Locator attachments (49). No statistically significant between-group differences were observed in that study either.

4.2 MANDIBULAR THREE-IMPLANT-ASSISTED OVERDENTURES AND ANTERIOR–POSTERIOR MOVEMENT

The results of the present study show that at baseline, 35% of patients perceived rocking movement with their mandibular two-implant-assisted overdenture. This movement decreased by 12% (from 35% to 23%) after conversion of the overdenture. This decrease in overdenture rocking movement is related to the biomechanical mechanism. Adding a midline implant to an existing mandibular two-implant-assisted overdenture creates a tripod support and an indirect retention, which decreases dislodging forces and thus hinge movement of the mandibular implant-assisted overdenture around the fulcrum line (42, 169, 204).

These findings are in line with the results of an in-vitro study designed to evaluate the extent of rocking movement under anterior loading in different designs of mandibular implant overdentures assisted by different numbers of implants (169). According to the results of that study, the two-implant-assisted overdenture showed significantly larger vertical displacement upon anterior loading (1.06 mm) in comparison to overdentures anchored by three

implants (0.64 mm). The authors concluded that the midline implant decreases the upward movement of the denture base at the posterior area upon anterior loading.

The anterior–posterior movement of implant overdentures has been also assessed previously in two clinical studies both conducted in the province of Quebec in Canada (61, 62). In these two clinical trials (61, 62), evaluation of the perceived rocking movement was made using self-reported questionnaires with Likert or VAS scales. The findings of the study performed by Emami et al. (62) showed that 18.5% of patients reported a rocking movement with their mandibular three-implant-assisted overdenture. This percentage is similar to the percentage seen in our study after the conversion (23%). The study of Kimoto et al. (61) included 79 edentate patients aged 72.3 ± 4.6 years wearing mandibular two-implant-assisted overdentures opposed by complete denture. In that study, quite similar to our baseline data, about 47% of the study participants perceived anterior–posterior movement with their mandibular overdenture. The study found a statistically significant correlation between the rocking movement, the length of the denture base, and the positioning of the anterior teeth. Patients with longer dentures were less likely to report rotational movement (61). Moreover, with every additional millimeter in the distance between the anterior border of the prosthesis and the incisal edge of the anterior teeth, there was 1.5 times more probability of reporting rocking movement.

In our study, the use of within-subject analysis[76]allowed us to compare the rocking movement

between two- and three-implant-overdenture. In rocking movement associated with three-implant overdenture, we found a difference between the results of expert-based and patient-reported assessment. Expert measurement was based on the 10-item Functional Assessment of Dentures (FAD) (175, 176). These criteria were introduced and validated by Corrigan et al. in 2002 (176). We used one of these criteria, the lower denture stability (anterior–posterior movement), for our clinical assessment. As opposed to clinical assessment, the pre–post conversion difference was not statistically significant in the subjective assessment. This difference can be explained by the fact that the subjective assessment relies on the individual's memory to recall the intensity of the movement before and after treatment. This could lead to a memory bias and lack of measure sensitivity (205). Moreover, the study participants may have overestimated the extent of the movement because of their high expectation regarding the performance of the three-implant-assisted overdenture. This could also explain why the study findings did not show a correlation between patient satisfaction post-score and the perception of rocking movement, in contrast with previous research (61, 62). Emami et al. (62) found a strong correlation ($p < 0.0001$, $r = 0.6$) between patients' perception of rotation and their ratings of general satisfaction. Patients who perceived rotational movement with their three-implant-assisted overdenture were less satisfied with their prostheses than those who did not perceive this movement (62). In the study of Kimoto et al. (61) although almosthalf of the patients (47%) reported a rocking

movement with two-implant-assisted overdentures, all of them were very satisfied with their prosthesis ($p < 0.0001$, $r = 0.6$) (61).

4.3 PATIENTS' WILLINGNESS TO PAY FOR THE MANDIBULAR THREE-IMPLANT-ASSISTED OVERDENTURE

In this study, we added a dimension to patient-oriented data by exploring how edentate individuals with the experience of having a mandibular two-unsplinted-implant overdenture would value the benefits of the conversion of their overdenture. Willingness to pay (WTP) has been considered as an important tool to examine the value of a treatment option or a health care technology from patients' perspectives (206). It represents patients' preferences regarding spending money for a health-care service (207). WTP assists both clinicians and patients in treatment decision-making (16). According to the literature, willingness to pay can be influenced by various factors such as individuals' socio-demographic characteristics, as well as their oral health conditions and needs (208). Impaired oral function could motivate patients' willingness to pay for dental implants (16, 173, 209). In our study, among the socio-demographic characteristics only sex was associated with patients' WTP.

Our results regarding sex difference are in agreement with the literature (208, 210-212). Women have higher health consciousness than men (212), they usually accord a higher value to

their oral health, and they also consume more healthcare services (213, 214).

Willingness to pay for mandibular two-implant-assisted overdenture has been examined previously (173, 215). According to the web survey conduced by Srinavasan et al. (215) in Montreal, 39 dentate individuals would be willing to pay a substantial amount to receive mandibular two-implant overdentures when they become edentate. In that survey, the out-of-pocket average WTP for implant overdentures was about $5,500 CAD, and WTP amounts increased if the patients were assured of the success of implant overdenture therapy.

The results of the study conducted by Esfandiari et al. (173), which included a convenience sample of 56 completely edentulous elders (68–79 years) from Montreal, showed that patients with previous experience of wearing two-implant-assisted overdentures would pay three times the cost of a conventional denture to receive an implant-assisted overdenture, in comparison to those who haven't had this experience. Furthermore, in that study, facilitating the mode of payment by monthly installments doubled the number of individuals willing to paying for dental implants (173).

In our study, after 6 weeks of using the three-implant-assisted overdentures, the percentage of patients who were willing to pay an additional cost for this treatment increased by 17%. This finding confirms the result of Esfandiari et al.(173) that having a positive experience or

having information about the benefit of a treatment could shape patients' preferences and willingness to pay for the treatment.

However, in contrast to the study of Esfandiari et al.(173), paying by the mode of monthly installments did not influence our patients' decision regarding their WTP for the three-implant-assisted overdentures. This could be related to the fact that our patients were very satisfied with their oral condition and the treatment that they received in the phase one of the trial (two-implant-assisted overdentures).

Although several studies in other health care disciplines have shown a positive relationship between willingness to pay and patient satisfaction with treatment (216, 217), in our study we did not find any correlation between the post-intervention WTP values for the three-implant-assisted overdentures and patients' satisfaction change scores.

This lack of association might be attributable again to the high level of satisfaction expressed by our study participants toward their two-implant overdenture. Thus, WTP might be influenced by their real oral health needs rather than their level of satisfaction (16, 173).

4.4 STUDY STRENGTHS AND LIMITATIONS

Our study had several strengths. We assembled a sample of patients who received an unloaded midline implant within a previous trial, which allowed us to conduct a second trial to show the

therapeutic difference of two types of removable implant-assisted overdentures within the same patients. To our knowledge, this study is the first clinical trial that was designed specifically to compare two- versus three-implant-assisted overdentures on patient-reported outcomes, thereby addressing a gap in the literature. In the design of such trials, the comparator presents a successful treatment according to the previous research. Furthermore, the analytic approach benefits from the homogeneity in various aspects such as study population and study setting. However, the results should be interpreted with caution due to certain study limitations. The first is the design of the trial as a single group pre–post quasi-experimental study which led to the absence of a control group and potential for response-shift bias (218). Response-shift is the change in an individual's evaluation of a construct due to a change in their internal standards of measurement, values, or definition of the construct (219-221). In other words, patients may give different responses on the patient-reported outcome measures over time, not only due to changes in their health, but also due to changes in their perception about what their health means to them (220), which may lead to internally invalid results (222). Secondly, the sample size was based only on the primary outcome. Finally, we only assessed the short-term outcomes at 6-week follow-up. Although in this approach, we eliminated the risk of memory bias, we were not able to evaluate the potential complications with three-implant-assisted overdenture with Locator attachments[81] in the long term.

4.5 FUTURE STUDIES

Further pragmatic and explanatory trials are needed to examine the effectiveness of three-implant-assisted overdenture in real practice conditions and under optimal situations, and to confirm the external and internal validity of these results. Long-term assessments of the effectiveness and efficacy of the three-implant-assisted overdenture from patients' perspectives are required to provide evidence for mandibular overdenture with maximum functional benefit and at an optimal cost. Further research is also needed to identify those sub-groups of patients that would benefit more from the three-implant overdenture—for example for those who have severely resorbed residual ridge, combined with maladaptation tendencies.

CHAPTER 5: CONCLUSIONS

The results of this clinical trial suggest that:

- For the majority of patients wearing a mandibular two-unsplinted-implant-assisted overdenture for 2 years, the addition of the midline locator supported by an implant significantly increases their satisfaction with the stability of the overdenture as well as their ability to chew hard food and to speak, and meets their expectations.
- The addition of a Locator supported by a midline implant could reduce the anterior–posterior movement of the two-implant-assisted overdenture as measured clinically. However, the patient-based measures may not be sufficiently sensitive to show this decrease in rocking movement from the patient's perspective.
- Patients' willingness to accept the mandibular three-implant-assisted overdenture is dependent on the amount of additional cost they would pay when compared to two-implant-assisted overdentures. This suggests that the two-implant-assisted overdenture should still be considered as the most cost-effective treatment option for rehabilitation of the edentate mandible.

- Further pragmatic and explanatory trials are needed to examine the effectiveness of three-implant overdenture in real practice conditions and under optimal situations to confirm the external and internal validity of these results.

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APPENDICES

APPENDIX I: CONSENT FORM

Université de Montréal

La satisfaction, la qualité de vie des édentés et la survie implantaire suite à une réhabilitation par mise en charge immédiate d'une prothèse totale mandibulaire reliée à deux implants endo-osseux non-jumelés

- Une étude pilote expérimentale -

Université de Montréal

Faculté de médecine dentaire
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ADDENDUM AU CONSENTEMENT ÉCLAIRÉ

Dans le cadre de l'étude intitulée «La satisfaction, la qualité de vie des édentés et le succès implantaire suite à une réhabilitation par mise en charge immédiate d'une prothèse totale mandibulaire reliée à deux implants endo-osseux non-jumelés, une étude pilote expérimentale» (certificat CERES#990), vous avez reçu une prothèse inférieure retenue par deux implants ainsi qu'un implant central dormant.

Nous allons, dans le cadre d'une suite à ce projet de recherche, convertir vos prothèses implanto-portées à 2 implants en prothèses à 3 implants en activant l'implant central afin de tester l'effet de cette modification sur votre satisfaction ainsi que sur les mouvements rotationnels de votre prothèse.

Le tableau ci-dessous présente les étapes de ce projet :

Visite	**Étapes de l'étude**	**Traitements/collectes de données**	**Durée (heure)**
1	Avant l'intervention	Explication du projet, Signature de l'addendum au consentement éclairé, évaluation des prothèses et revérifier les données 2 ans, poser des nouvelles gaines sur implants latéraux.	1.5
2	Conversion des prothèses (après 2 semaines)	Évaluation de nouvelles gaines par des questionnaires, Conversion des prothèses à 2 implants en prothèses à 3 implants par mise en place de la troisième Locator et regarnissage du 3^{ième} Locator et 3^{ième} gaine.	1,5
3	Suivi après 6 semaines	Évaluation de nouvelles prothèses : entrevues enregistrées et questionnaires : (processus de la mise en charge immédiat et 3 implants)	3.0

- Il est possible que vous éprouviez de l'inconfort suite au changement ou que votre prothèse tienne en place plus fermement. Si cela venait à se produire, les prothèses seraient ajustées. Nous voulons aussi vous informer que les étudiants en maitrise qui ont participé à la première phase de ce projet ont gradué et terminé

leurs études. Le traitement sera donc effectué par un/une clinicien(ne) ayant un permis de travail de l'ordre des dentistes du Québec.

- La partie des implants servant à retenir la prothèse inférieure va s'user avec le temps, À la fin de l'étude, tout suivi devra être effectué en bureau privé. En tout temps, au cours de l'étude, il vous sera possible de rejoindre un(e) dentiste-chercheur(euse) si vous avez un inconfort ou des questions.

- On vous demandera de défrayer une partie des coûts des matériaux et les pièces prothétiques pour la conversion de votre prothèse (250,00 $). Cette participation pourrait vous occasionner des dépenses (stationnement, essence, taxis) qui ne vous seront pas remboursées.

- Vous êtes libre d'accepter ou de refuser de participer à ce projet de recherche. Vous pouvez vous retirer de cette étude à n'importe quel moment, sans avoir à donner de raison. Vous avez simplement à aviser la personne ressource de l'équipe de recherche et ce, par simple avis verbal.

- Pour toute préoccupation sur vos droits ou sur les responsabilités des chercheurs concernant votre participation à ce projet, vous pouvez contacter le conseiller en éthique du Comité d'éthique de la recherche en santé (CERES) par courriel: ceres@umontreal.ca ou par téléphone au (514) 343-6111 poste 2604 ou consulter le site: http://recherche.umontreal.ca/participants.

- Toute plainte concernant cette recherche peut être adressée à l'ombudsman de l'Université de Montréal, au numéro de téléphone (514) 343-2100 ou à l'adresse courriel ombudsman@umontreal.ca. L'ombudsman accepte les appels à frais virés. Il s'exprime en français et en anglais et prend les appels entre 9h et 17h.

Déclaration d'addendum au consentement éclairé

Engagement et signature du (de la) participant(e):

Je déclare avoir pris connaissance et compris le présent addendum au consentement éclairé.

Je reconnais qu'on m'a expliqué cet addendum, qu'on a répondu à mes questions à ma satisfaction et qu'on m'a laissé le temps voulu pour prendre une décision.
Je consens à participer à la suite de ce projet de recherche aux conditions qui y sont énoncées. Une copie signée et datée du présent addendum me sera remise.

_____

Nom et signature du participant(e) *Date :*

Engagement et signature du(de la) dentiste-chercheur(euse):

Je certifie qu'on a expliqué au participant les termes de l'addendum au consentement éclairé, que l'on a répondu aux questions que le participant avait à cet égard et qu'on lui a clairement indiqué qu'il demeure libre de mettre un terme à sa participation, et ce, sans aucune conséquence négative.

Je m'engage avec l'équipe de recherche à respecter ce qui a été convenu à l'addendum et à en remettre une copie signée au participant.

_____ _____

Nom et signature du (de la) dentiste-chercheur(euse) *Date :*
responsable du projet de recherche

APPENDIX II: DENTURE ASSESSMENT QUESTIONNAIRE (PRE)

ASSESSMENT OF PROSTHESIS (PRE)

Date : ☐☐☐☐ / ☐☐ / ☐☐
y y m m d d

First and last name: _____

We would like to know how satisfied you are with your present prosthesis. For each of the following questions, mark the response that you feel is the best. In the case where a question doesn't apply to you, for example if you don't eat a certain type of food, please indicate this just below the question

1. Ease of cleaning

1. a On a scale from 1 to 6, how difficult it is to clean your **lower** prosthesis and mouth?

O 1	O 2	O 3	O 4	O 5	O 6
(Not at all difficult)					**(Extremely difficult)**

1. b How difficult it is to clean your **lower** prosthesis and mouth?

Extremely difficult _____ Not at all difficult

2. General satisfaction

2. a On a scale from 1 to 6, in general, are you satisfied with your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6
(Extremely satisfied)					**(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

3. Ability to speak

3. a On a scale from 1 to 6, how difficult it is for you to speak because of your lower prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6
(Not at all difficult)					**(Extremely difficult)**

3. b How difficult it is for you to speak because of your lower prosthesis?

Extremely difficult _____ Not at all difficult

1 / 7

4. Comfort

4. a On a scale from 1 to 6, are you satisfied with the comfort of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

5. Aesthetics

5. a On a scale from 1 to 6, are you satisfied with the appearance of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

6. Stability

6. a On a scale from 1 to 6, are you satisfied with the stability of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

6. b Are you satisfied with the stability of your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied

6. c Does your **lower** prosthesis raise at the back when you chew?

No ○ 1 Yes ○ 2

6. d If yes, how much does this raising bother you?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Not at all bothered) **(Extremely bothered)**

6. e If yes, how much does this raising bother you?

Extremely bothered _____ Not at all bothered

7. Ability to chew

7. a On a scale from 1 to 6, in general, how difficult is for you to chew food?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. b Please, indicate in general, how difficult is for you to chew food?

Extremely difficult _____ Not at all difficult

7.c On a scale from 1 to 6, how difficult is for you to chew **fresh white bread**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7.d Please indicate how difficult is for you to chew **fresh white bread**.

Extremely difficult _____ Not at all difficult

7.e On a scale from 1 to 6, how difficult is for you to chew **hard cheese**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. f Please indicate how difficult is for you to chew **hard cheese**.

Extremely difficult _____ Not at all difficult

7. g On a scale from 1 to 6, how difficult it is for you to chew **raw carrots**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. h Please indicate how difficult is for you to chew **raw carrots**.

Extremely difficult _____ Not at all difficult

7. i On a scale from 1 to 6, how difficult it is for you to chew **dry salami**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. j Please indicate how difficult is for you to chew **dry salami**.

Extremely difficult _____ Not at all difficult

7.k On a scale from 1 to 6, how difficult it is for you to chew **sliced steak**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. l Please indicate how difficult is for you to chew **sliced steak.**

Extremely difficult _____ Not at all difficult

7. m On a scale from 1 to 6, how difficult it is for you to chew **raw apples**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. n Please indicate how difficult is for you to chew **raw apples**.

Extremely difficult _____ Not at all difficult

7. o On a scale from 1 to 6, how difficult is for you to chew **lettuce**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. p Please indicate how difficult is for you to chew **lettuce**.

Extremely difficult _____ Not at all difficult

8. Function

8. a On a scale from 1 to 6, in general, is your food well chewed before swallowing?

O 1	O 2	O 3	O 4	O 5	O 6

(Very well chewed) **(Badly chewed)**

8. b In general, is your food well chewed before swallowing?

Badly chewed _____ Very well chewed

8. c Which food do you have difficulties in chewing before swallowing?

_____

_____

_____

9. Ease of removing

9.a On a scale from 1 to 6, how difficult is for you to remove your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

9. b Please indicate how difficult is for you to remove your **lower** prosthesis.

Extremely difficult _____ Not at all difficult

10. Ease of insertion

10. a On a scale from 1 to 6, how difficult is to insert your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

10. b Please indicate how difficult is to insert your **lower** prosthesis.

Extremely difficult _____ Not at all difficult

11. Oral condition

11. a On a scale from 1 to 6, in general, are you satisfied with your oral condition?

O 1	O 2	O 3	O 4	O 5	O 6

(Extremely satisfied) **(Not at all satisfied)**

11. b In general, are you satisfied with your oral condition?

Not at all satisfied _____ Extremely satisfied

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

No ○1 Yes ○2

11. d If yes, why?

_____

_____

_____

_____

_____

12. Expectation

12. a On a scale from 1 to 6, how satisfied do you think you will be with the activation of the third midline implant?

○1	○2	○3	○4	○5	○6

(Extremely satisfied) **(Not at all satisfied)**

12. b Please indicate how satisfied do you think you will be with the activation of the third midline implant.

Not at all satisfied _____ Extremely satisfied

12. c I expect that the addition of the third implant will influence positively:

The stability of my lower denture	No ○1	Yes ○2
The retention of my lower denture	No ○1	Yes ○2
The comfort with my lower denture	No ○1	Yes ○2
My ability to chew	No ○1	Yes ○2
My ability to speak	No ○1	Yes ○2
My ability to swallow	No ○1	Yes ○2

Others: _____

13. In short

If you have difficulties with your prosthesis, what is the major problem?

_____

_____

_____

_____

_____

14. Cost

14. a In general, how much would you be willing to pay to receive a three-implant overdenture?"

( ) $

14. b Would you be willing to pay $2,000 more to activate the third implant?"

Yes ○1 No ○2

14.c Why? Please explain

_____
_____
_____
_____
_____

14. d "How much would you be willing to pay to activate third implant?"

( ) $

14. e Do you think that the mode of payment (monthly instalments) would affect your decision in this regard?

Yes ○1 No ○2

14. f If the cost of three-implant denture was the same with two-implant overdenture, would you choose receive three-implant overdenture??

Yes ○1 No ○2

14.g Why? Please explain

_____
_____
_____
_____
_____

APPENDIX III: DENTURE ASSESSMENT QUESTIONNAIRE (223)

ASSESSMENT OF PROSTHESIS (POST)

Date : ☐☐☐☐ / ☐☐ / ☐☐
y y m m d d

First and last name: _____

We would like to know how satisfied you are with your present prosthesis. For each of the following questions, mark the response that you feel is the best. In the case where a question doesn't apply to you, for example if you don't eat a certain type of food, please indicate this just below the question

1. Ease of cleaning

1. a On a scale from 1 to 6, how difficult is for you to clean your **lower** prosthesis and mouth?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

1. b How difficult is for you to clean your **lower** prosthesis and mouth?

Extremely difficult _____ Not at all difficult

2. General satisfaction

2. a On a scale from 1 to 6, in general, are you satisfied with your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Extremely satisfied) **(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

3. Ability to speak

3. a On a scale from 1 to 6, how difficult is for you to speak because of your lower prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

3. b How difficult is for you to speak because of your lower prosthesis.

Extremely difficult _____ Not at all difficult

1 / 7

4. Comfort

4. a On a scale from 1 to 6, are you satisfied with the comfort of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

5. Aesthetics

5. a On a scale from 1 to 6, are you satisfied with the appearance of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

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

Not at all satisfied _____ Extremely satisfied

6. Stability

6. a On a scale from 1 to 6, are you satisfied with the stability of your **lower** prosthesis?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Extremely satisfied) **(Not at all satisfied)**

6. b Are you satisfied with the stability of your **lower** prosthesis?

Not at all satisfied _____ Extremely satisfied

6. c Does your **lower** prosthesis raise at the back when you chew?

No ○ 1 Yes ○ 2

6. d If yes, how much does this raising bother you?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

(Not at all bothered) **(Extremely bothered)**

6. e If yes, how much does this raising bother you?

Extremely bothered _____ Not at all bothered

7. Ability to chew

7. a On a scale from 1 to 6, in general, how difficult is for you to chew food?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. b Please indicate, in general, how difficult is for you to chew food?

Extremely difficult _____ Not at all difficult

7. c On a scale from 1 to 6, how difficult is for you to chew **fresh white bread**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. d Please indicate how difficult is for you to chew **fresh white bread.**

Extremely difficult _____ Not at all difficult

7. e On a scale from 1 to 6, how difficult is for you to chew **hard cheese**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. f Please indicate how difficult is for you to chew **hard cheese.**

Extremely difficult _____ Not at all difficult

7. g On a scale from 1 to 6, how difficult is for you to chew **raw carrots**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. h Please indicate how difficult is for you to chew **raw carrots**.

Extremely difficult _____ Not at all difficult

7. i On a scale from 1 to 6, how difficult is for you to chew **dry salami**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. j Please indicate how difficult is for you to chew **dry salami**.

Extremely difficult _____ Not at all difficult

7. k On a scale from 1 to 6, how difficult is for you to chew **sliced steak**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. l Please indicate how difficult is for you to chew **sliced steak.**

Extremely difficult _____ Not at all difficult

7. m On a scale from 1 to 6, how difficult is for you to chew **raw apples**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. n Please indicate how difficult is for you to chew **raw apples.**

Extremely difficult _____ Not at all difficult

7. o On a scale from 1 to 6, how difficult it is for you to chew **lettuce**?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

7. p Please indicate how difficult it is for you to chew **lettuce.**

Extremely difficult _____ Not at all difficult

8. Function

8. a On a scale from 1 to 6, in general, is your food well chewed before swallowing?

O 1	O 2	O 3	O 4	O 5	O 6

(Very well chewed) **(Badly chewed)**

8. b In general, is your food well chewed before swallowing?

Badly chewed _____ Very well chewed

8. c Which food do you have difficulties in chewing before swallowing?

_____

_____

_____

9. Ease of removing

9. a On a scale from 1 to 6, how difficult is for you to remove your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

9. b Please indicate how difficult is for you to remove your **lower** prosthesis.

Extremely difficult _____ Not at all difficult

10. Ease of insertion

10. a On a scale from 1 to 6, how difficult is for you to insert your **lower** prosthesis?

O 1	O 2	O 3	O 4	O 5	O 6

(Not at all difficult) **(Extremely difficult)**

10. b Please indicate how difficult is for you to insert your **lower** prosthesis.

Extremely difficult _____ Not at all difficult

11. Oral condition

11. a On a scale from 1 to 6, in general, are you satisfied with your oral condition?

O 1	O 2	O 3	O 4	O 5	O 6

(Extremely satisfied) **(Not at all satisfied)**

11 b In general, are you satisfied with your oral condition?

Not at all satisfied _____ Extremely satisfied

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

No ○1 Yes ○2

11. d If yes, why?

_____

_____

_____

_____

_____

12. Expectation

12. a On a scale from 1 to 6, how satisfied you are with the activation of the third midline implant?

○1	○2	○3	○4	○5	○6
(Extremely satisfied)					**(Not at all satisfied)**

12. b Please indicate how satisfied you are with the activation of the third midline implant

Not at all satisfied _____ Extremely satisfied

12. c The addition of the third implant has positively influenced:

The stability of my lower denture	No ○1	Yes ○2
The retention of my lower denture	No ○1	Yes ○2
The comfort with my lower denture	No ○1	Yes ○2
My ability to chew	No ○1	Yes ○2
My ability to speak	No ○1	Yes ○2
My ability to swallow	No ○1	Yes ○2

Others: _____

12. d In general, would you recommend the three-implant overdenture to the edentate people (your family, friend or colleague etc.)?

Yes ○1 No ○2

13. In short

If you have difficulties with your prosthesis, what is the major problem?

_____

_____

14. Cost

14. **a** In general, how much would you be willing to pay for the received three-implant overdenture?''

( ) $

14. b Would you be willing to pay $2,000 more for the activation of the third implant?''

Yes ○1 No ○2

Why? Please explain

14. c ''How much would you be willing to pay for the activation of the third implant?''

( ) $

14. d Do you think that the mode of payment (monthly instalments) would affect your decision in this regard?

Yes ○1 No ○2

14. e If the cost of three-implant denture was the same with two-implant overdenture, would you have chosen receive three-implant overdenture?

Yes ○1 No ○2

Why? Please explain