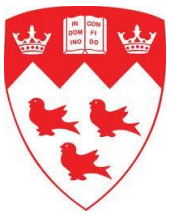
Single-implant overdentures retained by the Novaloc attachment system: a randomized cross-over trial

By:

Areej Nabil Abdel Jabbar



Faculty of Dentistry

McGill University

Montreal, Quebec, Canada

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Table of Contents

Abstract

Aim: This thesis reports the initial stage of a randomized cross over trial on the novel Novaloc (NL) attachment compared to Locator (LO), on a single implant mandibular overdenture (SIMO) for the edentulous elderly. It focuses on trial viability, recruitment and sample characteristics. It also describes preliminary comparisons of patient satisfaction and oral health related quality of life (OHRQoL) between the NL and LO groups.

Methods: Enrollment follows eligibility criteria that are close to those used in clinics for implant overdentures. Each participant was assigned to receive a single implant (lower midline) and randomly allocated to receive either NL or LO for 3 months. The trial includes another follow-up after an additional 3 months (attachments are changed); however, this thesis describes only the baseline and 1st follow-up data. Patient satisfaction with lower dentures was quantified by questions (answers on a 10 cm VAS, 10= completely satisfied) about *general satisfaction (primary outcom*e), as well as comfort, ease of cleaning, aesthetics and function (i.e. denture stability, ability to speak and chewing ability). The OHIP-EDENT questionnaire quantified OHRQoL, with higher scores denoting better OHRQoL. Data analysis per stage was carried out using mean differences and 95% confidence intervals.

Results: Thirty-eight patients were screened, and 17 were included. Currently, 38% of the estimated sample (n=10 of 26; 6 F, 4 M) were considered at baseline, and n=9 at the 3-month follow up. Mean *general satisfaction* (standard deviations) for patient receiving the NL and the LO at baseline was: 6.5 (3.9) and 9.1 (0.5) cm, respectively. After 3 months, mean ratings were 9.2 (1.0) with NL and 8.6 (1.9) cm with LO. Mean OHIP-EDENT scores were 77 (24) with NL

and 95 (21) with LO at baseline, and 109 (7) and 104 (5) after 3 months using NL and LO, respectively. Except for two satisfaction questions at baseline ("*ease of cleaning*" and the "*ability to chew-hard cheese*"), no variable showed a between-group significant difference.

Conclusion: This report confirms study viability by showing a steady recruitment rate in an adequate timeframe. It also suggests a low dropout rate in the future. Minor imbalance at baseline would be expected at this point, given data distribution in such a small sample (i.e. a single outlier, in the NL group). Post-treatment results (after 3 months) show no significant difference between both attachments, regarding both general satisfaction and OHRQoL. Although we are not able to reach a conclusive result or answer for which attachment is superior, four out of five participants preferred NL after using both attachments (6-mo follow-up). This re-enforces the need to complete the study to confirm or discard any clinically relevant difference between NL and LO**.**

Résumé

Prothèses amovibles implanto-retenues par le système d'attachement à implant unique Novaloc : un essai clinique croisé randomisé.

Objectif : Notre thèse rapporte la phase initiale d'un essai clinique croisé randomisé sur les prothèses amovibles implanto-retenues par le nouveau système d'attachement à implant unique Novaloc (NL) comparé au système Locator (LO) chez les personnes âgées édentées. Elle se concentre sur la faisabilité de l'essai, le recrutement et les caractéristiques de l'échantillon. Elle décrit également les comparaisons préliminaires concernant la satisfaction des patients et la qualité de vie liée à la santé bucco-dentaire (QVLSBD) entre les groupes NL et LO.

Méthodes : Le recrutement suit des critères d'éligibilité proches de ceux utilisés en clinique pour les prothèses dentaires implanto-portées. Chaque participant a reçu un seul implant (symphysaire) et a été réparti au hasard pour recevoir soit le groupe NL soit le groupe LO pendant 3 mois. L'essai comprend un autre suivi après 3 mois supplémentaires (les systèmes d'attachements sont inversés) ; cependant, cette thèse ne décrit que les données de base et le premier suivi. La satisfaction des patients concernant leur prothèse dentaire mandibulaire a été quantifiée par des questions (réponses sur un EVA de 10 cm, 10= complètement satisfait) sur la satisfaction générale (résultat principal), ainsi que sur le confort, la facilité de nettoyage, l'esthétique et la fonction (c'est-à-dire la stabilité de la prothèse, la capacité à parler et à mastiquer). Le questionnaire OHIP-EDENT a quantifié la qualité de vie liée à la santé bucco-dentaire les scores les plus élevés indiquant une

meilleure QVLSBD. L'analyse des données par étape a été effectuée en utilisant les différences moyennes et des intervalles de confiance à 95 %.

Résultats : Trente-huit patients ont été examinés, et 17 ont été inclus. Actuellement, 38% de l'échantillon estimé (n=10 sur 26 ; 6 F, 4 M) ont été pris en compte au départ, et n=9 au suivi à 3 mois. La satisfaction générale moyenne (écart-type) des patients ayant reçu la NL et la LO au départ était de 6,5 (3,9) et 9,1 (0,5) cm, respectivement. Après 3 mois, les notes moyennes étaient de 9,2 (1,0) cm pour la NL et de 8,6 (1,9) cm pour la LO. Les notes moyennes de l'OHIP-EDENT étaient de 77 (24) avec NL et 95 (21) avec LO au départ, et de 109 (7) et 104 (5) après 3 mois avec NL et LO, respectivement. À l'exception de deux questions de satisfaction au départ ("facilité de nettoyage" et "capacité à mâcher du fromage à pâte dure"), aucune variable n'a montré de différence significative entre les groupes.

Conclusion : Ce rapport confirme la faisabilité de l'étude en montrant un taux de recrutement constant dans un délai adéquat. Il suggère également un faible taux d'abandon pour l'étude à venir. Un léger déséquilibre au départ est à prévoir à ce stade, compte tenu de la distribution des données dans un échantillon aussi restreint (c'est-à-dire une seule valeur aberrante, dans le groupe NL). Les résultats post-traitement (après 3 mois) ne montrent aucune différence significative entre les deux attachements, tant en ce qui concerne la satisfaction générale que la QVLSBD. Bien que nous ne soyons pas en mesure d'obtenir un résultat ou une réponse concluante pour laquelle l'attachement est supérieur, quatre participants sur cinq ont préféré NL après avoir utilisé les deux attachements (suivi de 6 mois). Cela renforce la nécessité de compléter l'étude pour confirmer ou infirmer toute différence cliniquement pertinente entre NL et LO.

Dedication

In the name of Allah, the most gracious, the most merciful.

This Thesis is dedicated to

My beloved husband: Yasser, my sweet little boy: Aous, my inspiration - my father: Nabil, my caring mother: Enas, my supportive and kind hearted sisters: Ola and Amina, my considerate brother: Ammar, my niece and nephews;:Layan, Hamad and Rashid, my thoughtful father and mother in-law: Maher and Soha, and to both my whole family and family in-law.

My closest friends in Jordan, UAE and Canada, and to everyone who genuinely stood by me and my family throughout this journey.

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Contribution of Authors

Areej Abdel Jabbar, MSc candidate, Faculty of Dentistry, McGill University, Montreal, Quebec, Canada**:** Written all chapters included in this thesis dissertation. Contributed to the screening process, data gathering and statistical analysis, scheduling appointments, assisting in both the surgical and prosthetic appointments. Participated in drafting the published manuscript for the study protocol attached in appendix E**.**

Dr. Raphael de Souza, Associate Professor, Division of Oral Health and Society, Faculty of Dentistry, McGill University, Montreal, Quebec, Canada: Designed and coordinated the study demonstrated in this thesis. Principal author in the published protocol. Managed the screening process, prosthetic steps, formulated the study forms and contributed primarily to the data analysis. Assisted in reviewing and guiding throughout the production of this thesis.

Dr. Nicolas Makhoul, Assistant Professor, Chief Department of Dentistry and Oral and Maxillofacial Surgery, Faculty of Dentistry, MUHC, McGill University, Montreal, Quebec, Canada: performed all the surgical procedures (implant placement and follow-up) concerned in the study. Involved in reviewing the protocol, screening process and confirmation of inclusion of patients.

Dr. Jocelyne Feine, Professor, Division of Oral Health and Society, Faculty of Dentistry, McGill University, Montreal, Quebec, Canada: Co-director of this thesis. Major work in the development of the study protocol. Oversight of study procedures. Assisted in reviewing and guiding throughout the production of this thesis.

Mr. Nicolas Drolet, Dr. Farah Manzoor, Ms. Gabrielle Mariano, Dr. Leonardo Aboud, Division of Oral Health and Society, Faculty of Dentistry, McGill University, Montreal, Quebec, Canada; **Research assistants** throughout the trial: facilitated the patients recruitment process, contacted the patients for scheduling appointments and follow-up updates, assisted the practitioner throughout the clinical appointments.

Dr. Lucie Rapp, PhD student, Paul Sabatier University, Toulouse, France: Wrote the French version of the abstract for this thesis.

List of Tables

List of Figures

Abbreviations

AAJ: Areej Abdel Jabbar

RFdS: Raphael Frietas de Souza

NMM: Nicolas Makhoul

SIMO: Single Implant Mandibular Overdentures

NL: Novaloc attachment

LO: Locator attachment

CD: Complete Denture

OHRQoL: Oral Health-Related Quality of Life

RCT: Randomized Cross-over Trial

F: Females

M: Males

SD: Standard Deviation

CI: Confidence Interval

PEEK: Polyetheretherketone

ADLC: Amorphous Diamond-Like Carbon

IOD: Implant Supported Overdentures

WHO: World Health Organization

VAS: Visual Analog Scale

MGH: Montreal General Hospital

CBCT: Cone Beam Computed Tomography

OHIP: Oral Health Impact Profile

PVS: Polyvinyl Siloxane

TiZr: Titanium Zirconium

IRB: Institutional Review Board

I. INTRODUCTION

Edentulism or complete tooth loss is a major irreversible condition that is most common in elderly communities [1-3]. The prevalence of edentulism varies considerably across different countries and ethnicities, showing a broad range among seniors [4, 5]. Most national surveys show no trend for a reduced prevalence over the years. The real global range may even wider however, given that some developing countries have insufficient oral health data [6]. Edentulism has a considerable adverse effect on quality of life by an evident causal pathway; lack of teeth leads to functional impairments and, in turn, to nutritional deficiencies and psychological damage [1, 2, 4, 6].

Conventional complete dentures (CDs) are presently the most common treatment method used for edentulism [7]. However, complaints concerning this treatment option are frequent, especially regarding mandibular CDs. CD wearers often complain of poor stability and retention in their dentures [7, 8], which demonstrates how this choice of treatment is inadequate to fully restore physical and psychosocial impairments.

The drawbacks associated with conventional CDs have led to the search and, finally, the introduction of different treatment options. Dental implants have arisen as an alternative treatment modality, mainly due to their favorable results and proven cost-effectiveness [9, 10]. Several studies have demonstrated an improvement in the pattern of bone loss in edentulous patients managed with implant-supported prostheses when compared to CDs [11]. Moreover, implant overdentures, specifically two-implant overdentures, have been proposed as the standard of care (or first-choice treatment) for the edentulous mandible [6, 8, 11, 12]. Studies have shown that two-

implant retained overdentures (IOD) are superior to complete dentures in a variety of aspects, including denture retention and stability, masticatory performance, patient satisfaction, oral health-related quality of life and appearance [11, 13-15]. However, this type of treatment is considered unfeasible for most patients, primarily because of the high cost.

A more recent concept, the single implant mandibular overdenture (SIMO), is a more affordable, less invasive and less time-consuming approach for the edentulous mandible [3, 11], with favorable properties and success rates [16, 17]. When compared to the mandibular two-implant retained overdentures, there were no significant differences between them regarding denture survival rate, oral health-related quality of life (OHRQoL) and patient satisfaction [3, 17-19].

The clinical success of a single implant mandibular overdenture is strongly dependent on the type and performance of the attachments used, which are usually prone to deterioration [15, 18, 20, 21]. Although most attachments used previously with SIMO (i.e. stud attachments) are considered advantageous in many aspects, they have been shown to require continual maintenance and frequent element replacement [18, 22-24]. That being said, newer designs and materials have been examined, aiming to introduce more suitable attachments. Potential improvements may lead to lower maintenance needs, lower costs and, consequently, greater patient satisfaction.

The newly developed Novaloc attachment system is considered a potentially promising attachment for SIMO due to its combination of a polyetheretherketone (PEEK) matrix and an amorphous diamond-like carbon (ADLC)-coated cylindrical patrix. Both components of the Novaloc are expected to provide this attachment system with better wear resistance when compared to traditional systems and, therefore, lower the maintenance needed.

We searched the literature and found no clinical trials assessing the functionality of these attachment systems or the components involved. Nevertheless, positive reflections regarding PEEK matrices have been shown in an *in vitro* study [25].

This thesis reports on initial data from a randomised cross-over clinical trial comparing the Novaloc attachment system on a SIMO with the conventional Locator attachment for elderly edentulous patients. The focus of the trial is the comparative effectiveness of both attachments in a SIMO (timespan: 3 months), with ratings of general satisfaction on visual analog scale (VAS) as the primary outcome. Secondary outcomes include OHRQoL, cost of treatment, clinician-based outcomes and choice of attachment.

II. BACKGROUND

II.1 Edentulism

II.1.1 Definition & Etiology

Edentulism is an irreversible, chronic condition defined as the complete absence of teeth. It can be the result of a combination of several factors, including dental-related diseases, lower selfcare/awareness seen in patients with age, low access to oral healthcare, lack of knowledge/instruction and other socioeconomic factors [1, 6, 7, 11, 26]. Periodontal diseases and carious lesions left untreated are the main dental issues leading to the loss of teeth. Moreover, the high cost of dental treatment raises a barrier for people with lower income to seek preventive procedures or early treatment [1, 2, 6, 27]. Systemic health problems and certain medications, such as painkillers, might aid in concealing the symptoms of certain dental conditions [2, 6]. Regarding public health, most countries do not include dental coverage within their health systems. Therefore, disadvantaged patients do not have access to most dental care facilities. In addition, caregivers who do not treat disadvantaged patients with respect hinders the sense of trust and security the community should have towards these professionals. Hence, some patients may be unlikely to seek the help they need [1, 6, 12, 27].

II.1.2 Epidemiology

Although the number of edentulous people in many countries has been declining and the extraction of compromised teeth has been considered the last choice of action, many seniors still suffer from this problem worldwide [2, 3, 6, 7, 11, 13]. The rate of edentulism differs across countries, areas and ethnicities even within the same country. The range, mostly targeting the elderly, was reported to be as wide as 6% to 69% [4, 5, 27]. In 2010, a study in Canada measuring the overall prevalence of edentulism yielded a percentage of 6.4%, and 21.7% in the age group from 60 to 79 years old [27].

Studies have shown contradicting results regarding the difference in the prevalence of edentulism between females and males [2]. Whereas certain studies revealed that there is no significant difference between females and males, others reflected a higher edentulism rate in females [2, 27]. The incidence of edentulism worldwide has been shown to gradually decrease throughout the last decades [1-3, 6, 7, 11, 27]. This is mainly because people today are often more able to afford dental visits, generally have higher educational levels and are more aware of the positive outcomes of maintaining their dental health [2, 11]. Yet, certain studies in the US predict an increase in the number of edentulous people in the near future due to the rising number of elderly people which might outpace the reduction [1, 2, 4, 6, 11, 12, 26, 27]. The latter points are seen as a result of: (1) people practicing a healthier lifestyle and, thus, living longer and becoming older [2, 11, 26, 27]; (2) the several remaining obstacles for the public to receive the proper oral health care, especially for the elderly [3, 7].

II.1.3 Impact of Edentulism

Patients who have lost their teeth are psychologically, physically and socially affected. Edentulism can lead to many complications: (a) bone loss, which is a continuous process and strong predictor for masticatory and facial aesthetics [11, 26, 27]. (b) Nutritional deficiencies; since edentulism restricts dietary intake in favor of processed foods, general health problems may result [2, 4, 11, 27]. (c) Psychosocial impairments; it was noted that edentulous patients have a hard time adjusting to daily activities that involve interaction with other people because of their compromised speech, painful chewing and altered facial features. Hence, social life and overall personal well-being are harmed by edentulism [2, 4, 27]. All points mentioned are expected to eventually worsen the OHRQoL of patients suffering from edentulism [2, 4, 27]. In summary, according to the World Health Organization (WHO) criteria; "The completely edentulous patient meets WHO criteria for being: (1) physically impaired, (2) disabled, and (3) handicapped"[26].

II.2 Removable Complete Dentures (CD)

II.2.1 Overview

Complete dentures (CDs) are classified as the conventional and most common method of treatment for edentulous patients [3, 6, 7]. Although dentures are considered an accessible and very affordable choice of care, many patients are dissatisfied with aspects of this treatment device [2, 3, 5-8].

II.2.2 Drawbacks & complaints

- Removable complete dentures have been linked to the following disadvantages [2, 3, 5, 6, 8, 12, 15, 20]:
    1) Poor stability and retention (especially during movement, and mainly in the mandible).
    2) Patients have a low tendency to fully adapt to them.
    3) Considered an inadequate option for patients with severely resorbed ridges.
    4) They don't have the ability to stop the process of alveolar bone loss (i.e. will be in constant need of replacement or relining/rebasing).
    5) Dietary intake and nutrition are negatively affected (especially when dentures do not fit properly).
    6) The aesthetics of patients might be compromised.

- The listed drawbacks and the higher need for better quality of life have motivated clinicians and researchers to promote and study alternative treatments involving implants [6].

II.3 Implant Overdentures (IOD)

II.3.1 Overview

Treatments involving prosthesis supported by osseointegrated implants were first proposed back in the 1980's. Since then, they have gained global recognition. They became more popular after being presented and proven to have successful outcomes by researchers in major conferences [6, 11, 22]. Patients with moderate to severe alveolar bone loss were believed to benefit the most from having dental implants to support/retain their dentures [6, 14, 15]. High survival and success rates

have been associated with implant overdentures. A number of study reviews revealed the following results: (a) the survival rate of dental implant overdentures has been shown to be 95% over a 20 year follow up; where specifically in the mandible the implant survival gave a percentage of 96.4%, (b) a 95% success rate with mandibular implant overdentures, (c) In a 10-year follow-up, a review showed an implant mean survival rate of 98% [5, 12, 15, 20, 22].

A group of studies concerning IODs agreed that the success of the prostheses and the implant was not affected by the number of implants used (two-implant retained compared with four-implant supported overdentures) [5, 22]. A higher demand for two-implant overdentures (2-IOD) was noticed soon after their release, mainly due to increased robust evidence supporting 2-implant retention for dentures [6, 9, 10, 12, 28]. Moreover, several reviews have reflected positive outcomes of this choice of treatment regarding reduced costs, improved function and increased personal satisfaction [3, 6, 9, 10, 12, 20, 29]. As a result, a consensus towards considering two-implant overdentures as the "standard method of treatment" was disseminated effectively [3, 6, 9, 10, 12, 22, 28].

II.3.2 Advantages

- Implant overdentures have shown to be advantageous in many ways [3, 5, 6, 12, 14, 15, 20, 30]:
    1) Improved retention and stability of complete dentures.
    2) Better mastication and function, in general.
    3) Patients have an improved psychosocial status.
    4) Increased patient satisfaction and better OHRQoL.

5) Ability to limit and control the bone loss of the ridge (bone preservation).
6) Very few serious complications and good overall prognosis.

II.3.3 Risk for Failures

Although IODs have proven to be highly successful, failures of implants are still possible. Those failures can be minimized through responsible case selection, diagnosis and proper disclosure of details of the treatment plan between the restorative and surgical teams [3, 5]. The following elements seem to be related to implant failures: (1) anatomical limitations; insufficient bone height, width or density, (2) poor oral health, (3) systemic diseases that compromise osseointegration, (4) harmful habits (i.e. alcoholism, smoking) and (5) lack of operator experience [3, 5, 8].

II.3.4 Drawbacks

While implant prosthesis can serve as the standard method of treatment for edentulous patients, they are still inaccessible for certain patients due to economic barriers, high maintenance requirements, anatomical limitations and the fear of surgery [3, 5-8, 11, 13]. Although the cost effectiveness of IODs has been shown, it is still considered a costly choice for many elderly patients. Moreover, most edentulous patients, in general, are financially underprivileged and have limited access to proper dental health care [3, 6-8, 11].

- **Complete dentures versus implant supported overdentures-summary:**

Implant overdentures are considered the standard care and a refined substitute for conventional complete dentures [6, 7, 15, 28]. They have gained superiority over CDs because of their advantageous properties. IODs offer improved mastication through; significantly higher stability and retention, limited alveolar bone resorption, especially for mandibular prostheses. Moreover, significantly greater patient satisfaction and better OHRQoL are associated with IODs when compared to conventional CDs [3, 6, 11-13, 15, 20, 29]. However, conventional CDs are still preferred by some edentulous patients because they are a more affordable and easily reachable treatment by the public [3, 6-8, 11, 13].

II.4 Single Implant Mandibular Overdentures (SIMO)

II.4.1 Overview

The constant growth of the elderly population has led to an expected increase in the demand for more affordable and accessible treatments. Researchers and practitioners are in constant search for an alternative treatment for edentulism to overcome the complaints and obstacles linked with conventional procedures. As a result, a new method of treatment that involves a single implant in the mandibular midline to retain an overdenture facing a conventional maxillary denture has been recently proposed [3, 22, 31]. Unfortunately, there is an insufficient amount of data regarding the effectiveness of single implant mandibular overdentures [3]. Nevertheless, several reviews have showed reliable positive outcomes for SIMOs, which justifies making it a potential alternative

treatment. The following results were demonstrated in some of the studies concerning SIMOs; (a) one study showed high success rates (91.7%) for SIMO at 1-year follow up [6], (b) survival and success rates were approximately similar to two-implant supported overdentures at a 5-year follow-up [18, 21, 32], (c) significantly greater patient satisfaction and quality of life when compared with conventional complete dentures, regardless of the implant materials or prosthetic methods used [3, 31], (d) most studies showed no implant failures [18], (e) High maintenance needed in the first year after the installment of SIMOs [21], (f) when compared to two-implant supported overdentures, SIMOs did not show a greater tendency for breakage [20, 33], (g) SIMOs showed a favorable degree of forces on the implant fixture when compared to fixtures in a two-implant retained prosthesis [8]. The possible advantages that have been related to SIMOs would mostly serve people with lower functional needs (i.e. elderly) [3, 6, 11, 22].

II.4.2 Advantages

- Potential superior properties for SIMOs [3, 6, 11, 18, 22, 31]:
    1) Surgically minimally invasive
    2) Fewer elements needed / simple design
    3) Lower costs
    4) Reduced operative time
    5) Low morbidity
    6) Results in higher ratings of patient satisfaction and OHQoL.

II.4.3 Drawbacks

- The following imitations are seen associated with SIMOs [3, 11, 21, 31]:
    1) High maintenance needs (constant need for replacement, especially in the first year).
    2) High possibility for fractures in the area of the denture bases that are reduced in thickness.
    3) Lack of enough evidence to support widespread provision of SIMOs and therefore, further investigations are needed to confirm their superiority over conventional dentures.

II.5 Attachment Systems

II.5.1 Overview

Attachment systems are essential components with a significant effect on the prognosis of any implant treatment. The stability, retention and overall performance of complete dentures are reinforced by the attachment systems used [15, 20, 30, 34]. There are various types of attachments, namely: bar-clip, magnet and stud (e.g. ball) attachments. They can be formulated to be either splinted or unsplinted. An example of a splinted one is the connected bar-clip attachment. On the other hand, ball and magnets can be used as unsplinted attachments [5, 11, 29, 30]. The majority of studies on SIMO involved stud attachments, mostly O-balls or cylindrical patrices [5, 15, 18, 19, 29, 30, 33, 35, 36]. Most attachments undergo common issues associated with continuous use: damaged or dislodged matrices, diminished retention over time and wear of components. Therefore, there will be a constant need for maintenance (including re-activation of matrices, if applicable), component replacement and adjustments, all with subsequent increase in the cost [11, 18, 34]. Most adjustments were required during the first year of attachment installation [15, 18, 21, 32]. It was proposed that such high maintenance can be reduced by implementing a larger O-

ball attachment (e.g. 5.9 mm-wide patrices) [21]. Nevertheless, the usage of such attachments demands a significant reduction in the thickness of denture bases and, therefore, increases the risk of denture fracture [18].

Dental practitioners should always aim to choose the type of attachment that results in the lowest complications. That being said, attachment systems with the following characteristics are preferable, especially for the elderly; (1) highly retentive, (2) highly wear resistant, (3) easy to maintain hygiene, (4) allows for comfortable denture use and (5) attachments that will not produce harmful stresses on the denture, implant and supporting tissues [28, 29, 34]. Since most of the attachment systems companies fail to reveal the properties of their products clearly and most studies provide little information regarding the various wear sequences that can be affected by several other factors (i.e. saliva, food), the selection of a proper attachment for patients tends to be challenging [11, 28, 32, 34]. Although the regular stud attachments commonly used are considered advantageous, scientists are looking into alternative attachment systems that are potentially more cost-effective, wear resistant and biocompatible.

II.5.2 The Locator Attachment System (Comparator)

- ***Overview:***

Most studies taking into consideration its limitations have agreed that the Locator attachment system, with its high retentive abilities, is a suitable and convenient choice for implant supported overdentures, specifically for SIMOs [16, 31, 32, 34, 37]. However, there was controversy

regarding their maintenance needs that would subsequently affect the retention. Previous studies of implant overdentures using Locator attachments were majorly limited by short follow-up periods and others done *in vitro*. Hence, the functioning of the Locator cannot be accurately predicted [16, 32, 34]. Regardless, it was concluded that: (a) the Locator attachment leads to high patient satisfaction, success rates and denture retention, but (b) the nylon matrix (male part) is easily prone to wear, and retention was compromised over time [16, 34]. As a result, researchers concluded that the Locator, when compared to ball attachments, would require frequent maintenance, more follow-ups and eventually higher expenses [34].

- ***Components of The Locator Attachment:***

The two main parts of the Locator attachment systems are;

1) **Patrix**: The Locator abutment, which is made of titanium alloy covered up with a layer of titanium nitrate (TiN; 2.0 to 5.0 μm in thickness). It comes in various dimensions depending on the case and the type of implant; while the cuff height ranges from 1.0 mm to 6.0 mm, the width of the cuff could be as narrow as 3.3 mm, 4.0 mm and 4.8 mm or as wide as 6.5 mm [32][52].

Figure 1. *Locator (comparator)* http://www.dentsplyimplants.com

2) **Matrix**: a nylon-made retentive insert embedded into a metallic housing. Inserts are known to have two sets of ranges – the regular range and the extended range (used for more

divergent implants). These come in various colors that reflect their different retention values. In the regular range that is most commonly used, the clear matrix is considered the most retentive one, the pink is intermediate, and the blue one has the lowest retention value. Based on the retention desired from a span of 1 to 5 pounds-force, the matrix color will be chosen [32, 34, 37] [52-55]

- ***Properties of the Locator attachment system*** **[30, 31, 34, 37]:**

1) They are considered to be "low-profile" attachments, because they have the advantage of being short in height, yet with a wide enough diameter to provide the necessary toughness and denture retention required.
2) They are beneficial for the completely edentulous elderly patients with narrow inter-arch areas.
3) Overdentures retained by the Locator attachment were found to be comfortably and simply placed/removed from the mouth by patients without compromising its retention.
4) The Locator provides relatively high retention without negatively affecting the implant, denture or intraoral supporting tissues.
5) It comes with inner and outer retentive features (i.e. dually retained). Moreover, mechanical and frictional retentive methods are used. Both help to deliver the optimum strength required for the Locator.
6) The Locator design provides space between the attachment cap and matrix, which ensures flexible mobility of the attachment in a vertical and fully rotational manner without affecting its retention.

7) The matrix is able to overcome and counterbalance a maximum of 20-degree implant angulation with the locator regular range or an angulation up to 40 degrees using the extended Locator matrix range.

II.5.3. The Novaloc Attachment System (Intervention)

- ***Overview:***

The Novaloc system - with its advanced design and materials - is an attachment that has been recently developed to overcome the disadvantages associated with previous stud attachment systems used with implant overdentures [3]. Based on a thorough literature search, clinical studies assessing this new attachment system and the materials associated with it have not been found. Nevertheless, an *in vitro* study revealed that the components of the matrices for the Novaloc system are potentially advantageous, especially when compared to the Locator attachment's matrices that are known for their frequent need for maintenance [25].

- ***Components of The Novaloc Attachment:***

The two main parts of the Novaloc attachment systems are composed of [38][56]:

1) **Patrix**: A titanium cylindrical abutment with an ADLC coating. Designed to be either straight or angled.
2) **Matrix:** composed of polyetheretherketone (PEEK). The retention of the matrices vary according to the color-coded range, starting from: (a) red insert; extra light retention of around 300gf, (b) white; 750gf and offers light retention, (c) yellow; medium retention of 1200gf, (d) green; a strong retention of approximately 1650 gf, (e) blue; a retention of 2100gf that is considered extra-strong, and finally (f) the black ultra-strong, 2250 gf retentive insert.

Figure 2. *Novaloc (intervention)* https://www.straumann.com

- ***Properties of the Novaloc attachment system:***

The new ADLC-coated cylindrical abutment of the Novaloc reduces surface roughness. Along with the PEEK matrix, increased wear resistance is expected along with better maintenance needs [25, 38].

III. RATIONALE

Directing this randomized clinical trial towards comparing novel attachment systems will enhance evidence-based guidelines for clinicians treating edentulous patients. Although SIMOs have a great potential to become the first choice of treatment for elderly patients, there are very few comparative studies in which they have been tested. The purpose of this research is to deliver clear information and clinical evidence to determine patient responses to the Novaloc system through a comparison with the Locator attachment. This study involves the use of a narrow diameter TiZr alloy single implant, which is beneficial in lowering the discomfort, associated costs and the possible conduct of additional procedures, such as bone augmentations. This minimally invasive single implant will primarily benefit the elderly edentulous patient community targeted in this trial. Most potential participants suffer from severely resorbed mandibular ridges and are limited from advanced/complex treatment modalities.

The Mixed Methods design of this full study will combine qualitative data gathered from interviews or focus groups involving the study participants with quantitative patient-based questionnaire data in a mixed-methods approach to clearly describe the patients' perceptions of both treatment choices. However, this thesis describes only the quantitative part of this research project, for trial feasibility and preliminary results.

- **Study Hypothesis:**

The null hypothesis proposed for this clinical trial states that there is no difference in ratings of patients' satisfaction between the new Novaloc and the Locator attachment systems.

IV. OBJECTIVES

The purpose of this thesis is to report initial data from our ongoing crossover mixed methods RCT on the recently developed Novaloc attachment used with SIMOs and compared to the standard Locator system. This study has recruited a sample of edentulous elderly patients wearing clinically adequate traditional complete dentures. Therefore, the goal of this study was to:

1. Provide in-depth information about the recruitment process for the RCT, focusing on the generalizability of the sample and study viability.
2. Gather preliminary evidence regarding the efficacy of the Novaloc compared to the Locator attachment at 3 months post-delivery. This comparison involved patients' general satisfaction with lower SIMOs (primary outcome). Secondary outcomes were:
   2.1. Oral health-related quality of life.
   2.2. Specific aspects of patient satisfaction, including denture stability, retention and ease of cleaning.
   2.3. Estimated treatment costs.
   2.4. Rotation of the SIMO, as perceived by the patient.
3. Clinician-based outcomes, such as the frequency of maintenance events, complications and success rates for each implant, each attachment and the overdenture.

V. METHODOLOGY

V.1 Overview

This thesis comprises the 1st part of a broader planned mixed-methods, randomized, superiority cross-over clinical trial conducted on elderly edentulous patients, who were assigned to receive two types of attachments over a single implant in the mandibular midline. The study sample selected had undergone detailed screening criteria in order to be accepted. The newly developed Novaloc system is being compared to Locators, the latter being an active comparator. Participants who received either system, assigned in a random manner, had their attachments evaluated and data gathered at baseline and after a three-month follow-up. The study design is depicted in Figure 3.

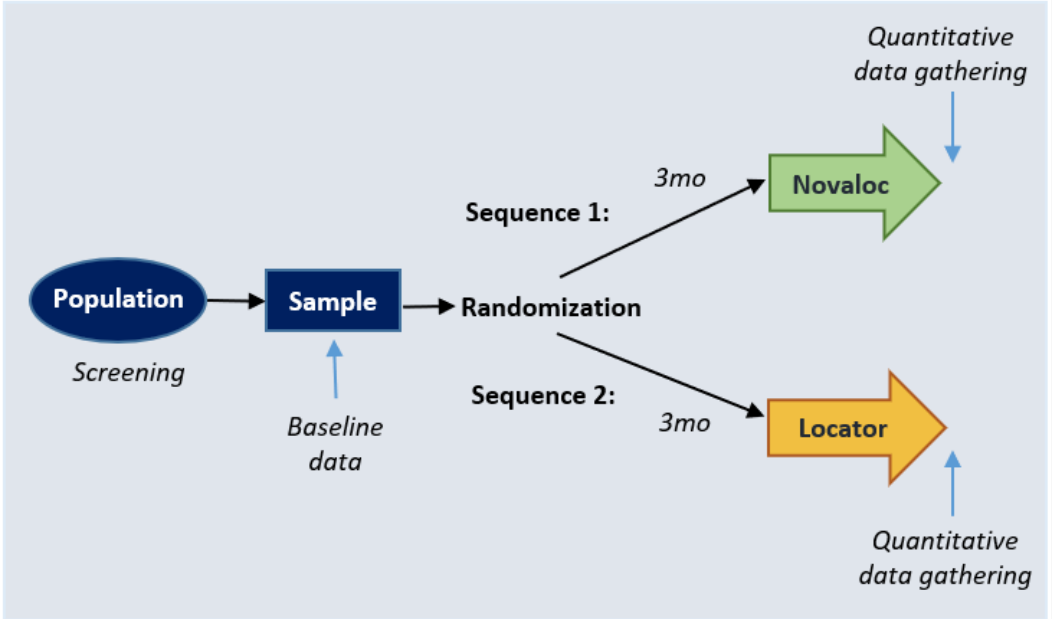

Figure 3. The design of the 1st part of the study undertaken in this thesis. Blue arrows represent data collection

Patients were recruited through: (1) written announcements (Appendix A.1, A.2) published in newspapers and the “Bel Age Magazine”, all published for the elderly population. (2) Handouts (Appendix A.3) were given to clinical instructors in the dental teaching clinics at McGill, requesting that they refer edentulous cases that could qualify for the trial. The announcements distributed included a small description of the study (using lay style), the contact information where interested patients could contact the research assistant by email or telephone. The research assistant provides potential candidates with information about the different aspects of the study. Furthermore, the research assistant organized the screening visits and subsequent appointments.

The trial is being carried out at two sites in Montreal depending on the stage of the study and procedures performed. Patient screening, surgical procedures (implant placement) and implant follow-up examinations are being carried out at the Oral and Maxillofacial Clinics in the Montreal General Hospital (MGH). The data collection, data analysis and prosthetic procedures, such as denture adjustments, attachments placement and maintenance, are all carried out at the teaching clinics in the Faculty of Dentistry, McGill University.

During the screening appointments, two researchers (AAJ; RFdS) explained the study to the patients. This part involved an in-depth explanation of surgical and prosthetic procedures, benefits and potential risks, the timeline of the study and the informed consent. Researchers also showed them schematic representations of implants and overdentures, as well as photos of the prosthetic components being tested. At the same time, a screening checklist and a cost data form were completed (Appendix B.1, B.2, B.3). The *screening form* contains questions regarding personal information (name, address, phone number, date of birth and age), the inclusion criteria and

exclusion criteria. Furthermore, patients who show the potential to be included received CBCT-scans (I-CAT FLX, Imaging Science International, Hatfield, PA, USA).

The *cost analysis data form* includes information such as; (a) The clinical time of the procedure performed by the clinician, assistant and laboratory, including completion of the consent form by the patient; (b) The consumable materials and equipment used; (c) Medications consumed; (d) Indirect costs that involve the patient, including the time in the waiting room, time off work, the method of transportation and the overall transport expenses.

Final decisions on inclusion/exclusion of each potential participant are taken after consideration of the screening checklist form, medical history and the CBCT image with the surgeon (NMM). Afterwards, the research assistant contacts the included patients to further explain the next steps and to arrange their implant placement appointments once their dentures are deemed functional.

V.2 Inclusion & Exclusion Criteria

V.2.1 Inclusion Criteria

- The following elements are considered:

1- 65 years old or more and are completely edentulous for more than six months.

2- Agree to receive implants to support their complete dentures.

3- Enough space in the mandible to fit a 3.3 mm wide implant in the midline.

4- Ability to sustain good oral and denture hygiene

5- No uncontrolled systemic diseases that might contraindicate minor oral surgery.

6- Understanding of spoken and written English or French.

7- Provision of written informed consent.

8- Acceptable upper and lower complete dentures. Evaluation criteria included: no tooth or base fracture, no or minimum tooth wear, adequate vertical dimension of occlusion and sufficient border extension. Potential participants with unsatisfactory dentures were referred for prosthetic adjustments or new dentures before inclusion.

V.2.2. Exclusion Criteria - Clinical

- Any of the occurrences below would lead to exclusion:

1- Need for frequent hospitalisation due to any serious medical condition.

2- Suffering from any impairment in cognitive function.

3- Inability to come to the planned study follow-ups.

4- History of radiation therapy in the orofacial region.

5- Conditions that may jeopardize the treatment, such as alcoholism or smoking (> than 10 cigarettes a day).

6- History of implant treatment

7- Acute or chronic symptoms of parafunctional or TMJ disorder.

V.2.3 Exclusion Criteria- Radiographic (CBCT)

- After the screening appointment, the CBCT images of potential participants were examined. They were excluded if they had:

1- Any area suggestive of bone pathologic lesions.

2- Less than 11 mm vertical bone height in the midline of the mandible.

3- Insufficient vertical bone width needed to fit the proposed implant.

4- Evidence of endosseous vascular structures in the planned implant site, as described by Kalpidis and Setayesh [39].
5- Mandibular ridges graded as class I or class II, according to Cawood and Howell [40].

V.3 Randomization, Allocation, and Blinding

The order in which patients received the specific type of attachment was determined using random computer-generated codes**.** The arrangement was based on the initial system used (ratio: 1:1): (1) AB; (2) B-A. These codes were kept in non-transparent sealed envelopes. Both the codes and envelopes were prepared following a simple randomization method, stratified by ridge morphology (favorable - Cawood and Howell's class III Vs. unfavorable/others) by a researcher that is uninvolved in patient selection and allocation, intervention and/or data collection. The envelopes are opened only at the appointment when the clinician inserts the attachment.

Obviously, it is not possible to blind the patients and care providers to the treatment. However, researchers who were unaware of the allocation sequence are conducting the outcome analysis whenever applicable. Moreover, participants are not informed about the expected performance of any of the attachments used, and appointments are set in order to minimize communication between participants.

V.4 Sequence of Procedures

V.4.1 Implant Placement Appointment - Surgical Procedure

Implant insertion follows a one-phase surgical protocol. Firstly, the patient is asked to sign a consent form provided by the nurse at the Montreal General Hospital (MGH). Afterwards, they are given a prophylactic antibiotic (Amoxicillin 2g, 1h before surgery) in order to prevent infection

[41]. Meanwhile, the nurse prepares the patient and the needed equipment for the surgery. Then, the surgeon: (1) administers the local anesthetic agent; (2) incises through the ridge mucosa and drills into the bone in the midline of the mandible; (3) inserts the implant in the midline following the implant kit instructions, appropriate labial-lingual position and angulation. The implant used in this trial is a Roxolid Standard Tissue Level implant (Straumann, Basel, Switzerland), made of a TiZr alloy, with 3.3 mm in width and length varying from 10 to 12 mm; (4) a healing/closure cap is placed on the implant; (5) Suture the incision; (6) give appropriate postoperative care instructions and prescribe the needed medications. Ibuprofen 400 mg - 800 mg is prescribed to be taken four times a day for two days if needed for postoperative pain. An alternative to the previously mentioned medication, Acetaminophen 500 mg - 1000 mg prescribed four times a day or Naproxen Sodium 375 mg or 550 mg prescribed twice a day. Lastly, the patient is scheduled by the secretary for a follow-up appointment two weeks later, as well as an appointment at the Faculty of Dentistry, McGill University, for the needed prosthetic adjustments. The patient is also asked not to wear his/her mandibular denture for two weeks, until the prosthetic appointment, in order to give the incision enough time to heal properly and lower the chances of postsurgical complications.

V.4.2 Denture Adjustment – Prosthetic Procedure

Patients are scheduled for this procedure two weeks after implant insertion. During this appointment at the McGill university clinics, a researcher (RFdS) drills in the fitting surface of the lower denture to have it fit over the implant/healing abutment in the midline and the sutured mucosa of the mandible. A PVS-based soft reline material (SofReliner Tough, Tokuyama Dental Corp., Tokyo, Japan) is filled in the hollowed fitting surface of the mandibular denture and placed over the mandible until it sets. Functional movements are done in the meantime. In other words,

the required modifications are carried out in order to make the fitting surface of the denture compatible with the mandible and the healing abutment. At this point, the research assistant arranges for the next appointment in 2-3 months with the patient for attachment installation.

V.4.3 Attachment Systems Installation – Prosthetic Procedure

In this appointment, patients are ready to receive one of the 2 types of attachments, according to random allocation codes. Before that, baseline data gathering is carried out. The participants fill in both the OHIP-20E Questionnaire (OHRQoL) and the McGill VAS Satisfaction questionnaire (excluding the data regarding the rotation of the mandibular overdenture) with the help of a research assistant. Once the patient has completed both forms and had the cost analysis data gathered, the treatment provider (RFdS) opens the sealed envelope for each participant with the attachment sequence (Locator → Novaloc, or vice-versa), and inserts the first attachments that will be worn for the next three months:

(A) Novaloc (Straumann): made of a polyetheretherketone (PEEK) capsule and an ADLC-coated cylindrical abutment. The matrices come in various colors representing different retention levels. In this study, only the yellow (medium retention) matrix is being used.

(B) Locator (Straumann): made of a nylon matrix and a TiN-coated abutment. As with the Novaloc attachments, different matrix colors reflect the retention. For this attachment, the pink (medium retention) matrix is used.

Common procedures for both attachments included selecting an abutment with external margins 1 mm above the mucosa. Abutments were torqued to 35 Ncm for both systems. Complete dentures

are then tested inside the mouth in centric occlusion, before and after using acrylic burs to create the extra space needed in the fitting surface of the lower denture. Lower dentures are trimmed with matrices assembled and using processing inserts and protective elastomeric rims, as recommended by the manufacturer. When the attachment ceases to interfere with the denture fit and occlusion, chairside hard denture reliner is applied (GC Reline; GC America Inc., Alsip, IL, USA) over the abutment, filling in the lower denture and placing it in centric occlusion until it sets. Then, the denture is removed, the protective rim is discarded and a straight bur is used to modify the relined area. Next, three different stages of finishing burs (green-gray-yellow) are used in order to finish and polish the polished and peri-implant (fitting) areas of the lower denture. Finally, the permanent matrix (yellow-Novaloc/pink-Locator) is installed, and the lower overdenture is delivered with postoperative care instructions given to the participant. In brief, participants are shown how to install and remove their implant overdenture. They are also requested to do it a few times in front of the researcher to be sure that they are comfortable with the process. Denture maintenance includes reinforcing previous instructions with specific advice: to brush the attachment site and the abutment/implant; never soak their overdentures in hypochlorite-based solutions or alcohol-containing mouthwashes.

V.5 Study Outcomes

In order to measure patient satisfaction, OHRQoL, associated costs, success and survival rates of the SIMO and implants, the following questionnaires/methods were used at baseline and at the 3-month follow-up:

V.5.1 McGill VAS Satisfaction questionnaire - Satisfaction with the overdentures

This questionnaire (Appendix C.1, C.2) is used to assess patient overall satisfaction and comfort, ease of cleaning, general satisfaction, aesthetics and function (i.e. ability to speak, ability to chew, and denture stability). These parameters are measured on 100 mm (10 cm) visual analogue scales (VAS) completed by the participant with the 0 cm end points of "Extremely difficult or Not at all satisfied", and the 10 cm endpoints of "Not at all difficult or Extremely satisfied". Participants will practice how to use this measuring technique on the first page of the questionnaire. The training page contains some percent numbers and 0-100% as anchor values. Regarding the patient's ability to chew and the denture's functionality, we as participants to rate their difficulty chewing specific types of food: fresh white bread, hard cheese, raw carrots, dry salami, sliced steak, raw apples and lettuce. These different food types range in texture from very hard (raw carrots) to very soft (fresh white bread).

V.5.2 OHIP-20E Questionnaire – Oral health related quality of life

This questionnaire (Appendix C.3, C.4) records edentulous patients' ratings of their oral health-related quality of life. The response categories form a 6-point Likert-type scale with frequency descriptors of *Always*, *Most of the time*, *Some of the time*, *Occasionally*, *Rarely and Never*. In this trial, 20 questions are posed. The questions target information regarding different physical, functional, social and psychological concerns associated with overdentures.

V.5.3 Estimated treatment cost

As described earlier, a cost analysis form is used to gather information regarding the clinical time, materials, medications and transportation expenses. The direct and indirect costs considered for

each participant's visit/procedure was gathered in order to measure the cost effectiveness of the attachment systems used.

V.5.5 Clinician-based Outcomes

These outcomes reflect the success rates and survival for the attachments at the 3-month follow-up for each participant. The clinician evaluates several aspects: (a) Presence of plaque and calculus. (b) Bleeding upon probing and the depth of peri-implant pockets. (c) Signs of swelling or inflammation. These aspects are thought to affect the performance of the attachment, and subsequently, the overdenture. Moreover, the frequency of the maintenance visits and the complications associated are considered in this assessment.

V.5.6 Rotation of the SIMO

This outcome is measured as part of the VAS Satisfaction questionnaire at post-intervention data gathering. Two questions evaluate patient-perceived rotation of the lower overdenture; (a) whether the denture lifts in the back while chewing (Yes/No), and (b) the extent to which lifting of the denture bothers the patient (10cm VAS).

V.6 Statistical Analysis

All of the participant's data extracted and gathered during the screening appointment, at baseline and at the 3-month follow-up are entered into separate Excel sheets for subsequent descriptive analysis. This analysis was carried out to show the paticipant's satisfaction with their SIMOs, generalizability of the sample and, thus, the integrity of the study implementation and progress. Baseline data were thoroughly described for this thesis. For final analysis, specific data showing a

significant deviation from normality will be transformed. Moreover, a composite variable has been formulated to address the number of clinical events per period. In order to test the effect of the intervention at the three-month follow-up, a mixed linear model was applied. Significance was set at $p \leq 0.05$.

V.7 Risks, Participant safety

Adverse effects and events seen at follow-ups or at any unplanned visits are closely monitored and reported in case of occurrence. Participants are informed that they are at risk of the usual sensitivity and post-operative pain seen with implant installation. Some of the possible complaints associated with implants and other minor oral surgical procedures include discomfort from the local anesthesia, soreness at the site of the procedure, swelling, redness and sensitivity or pain in the oral mucosa. Regarding the prosthetic part, the following issues have been identified that could arise: discomfort from the new or relined denture (including after attachment insertion), ill-fitting dentures, broken dentures or denture teeth and loosened attachment parts and implants. Those events will be managed within the course of the trial. Replacement of failed implants or attachment parts, denture repairs and replacements are planned whenever needed. In the case of a failed implant, patients are given the choice to redo the treatment another time with no expense. However, if they refuse, the clinician will offer to re-convert the lower denture to a conventional one.

V.8 Confidentiality

All acquired patient data are fully confidential. In order to achieve that, participants receive identification numbers that are used throughout the research, instead of their actual names. Any

spreadsheet with study data will identify the participants by those numbers only. Moreover, participant's files are held in a locked cabinet at the principal investigator's office at all times.

VI. RESULTS

VI.1 Screening process

A total of 38 individuals replied to study ads and attended research screening appointments. Figure 4 depicts the screening process throughout time. Most individuals were screened from the winter to the summer of 2018, with a 35% percentage of inclusion (respondents to advertisements in senior magazines). Subsequent screening efforts resulted in a better inclusion rate, given the adoption of a different strategy (contacting former patients from the McGill University undergraduate dental clinic).

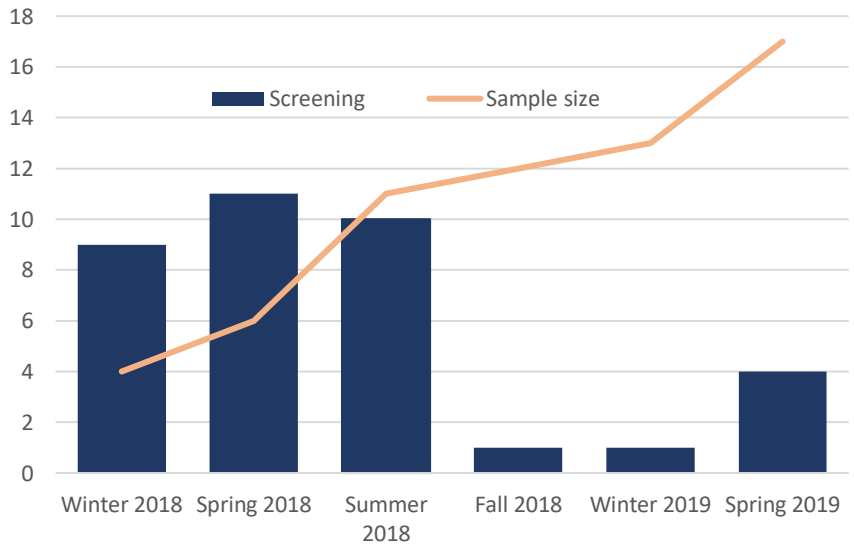

Figure 4. Number of screened individuals per season, and cumulative number of included participants (sample size).

VI.2 Participant sample

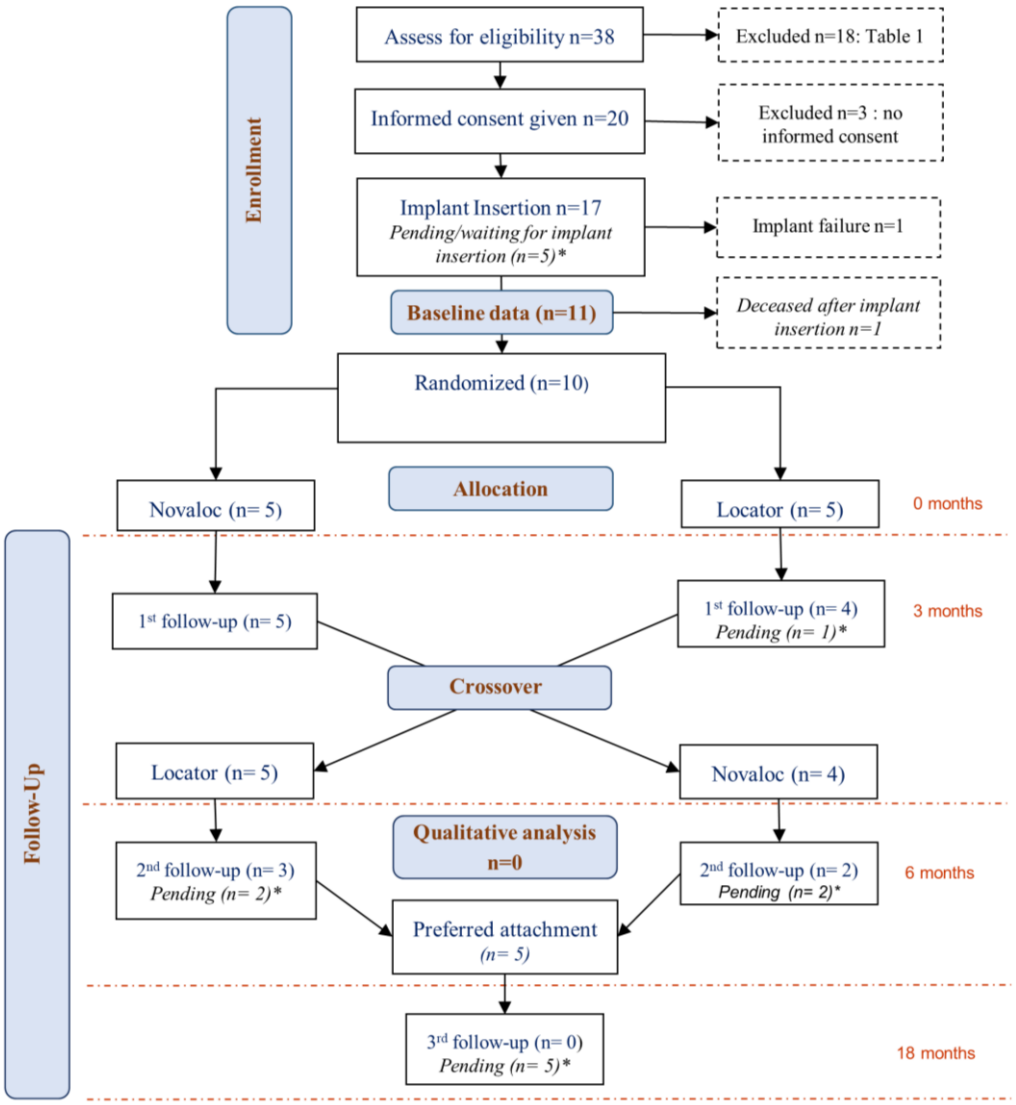

Figure 5. Participant flowchart. Number of included, withdrawn and lost participants are reported at each follow-up.

** Pending participants are waiting to undergo certain appointments and constitute no dropout.*

Our current study sample is comprised of 17 participants (35% of screenings). A trial flow chart, illustrating inclusion and exclusion of potential participants is shown in Figure 5. Before screening, three individuals showed interest in the study but did not want to sign the consent form. They were not counted in the trial flow chart. During the clinical exam, 18 were not included. Reasons for non-inclusion for 14 participants involved: systemic health issues, cost of maintenance, inability to return to recall visits, history of radiotherapy, heavy smoking, and disapproval of implant placement. Individuals were referred for CBCT scan, and four more were excluded. The sole reason for exclusion, based on radiographic criteria, is insufficient bone height. The detailed number of excluded patients with the corresponding reasons are listed in Table 1.

Table 1. Reasons for exclusion of participants after screening. Note: Some are listed in more than one category because they had multiple reasons for exclusion.

Excluded Participants (n)	Reasons for Exclusion
5	Systemic conditions contraindicating minor oral surgery
4	Vertical bone height < 11 mm (assessed by CBCT)
3	Unable to return for study visits
3	Refused implant stabilization (a): fear of surgery
2	Refused implant stabilization (b): declined due to the cost of maintenance
2	History of radiotherapy
1	Refused implant stabilization (c): did not want to adjust their dentures
1	Heavy smoker
1	Refused implant stabilization (d): refused to receive an implant
1	Lost contact after screening/before implant placement

VI.3 Sex

Throughout the screening process, an equal number of female and male participants were interested in the proposed study. This male: female proportion was maintained during participant inclusion. The number of randomized participants per sex reflects a balanced proportion. A summary of the exact proportions of both sexes at the different study stages is shown in Figure 6.

Figure 6. Number of females vs. males out of the total screened/included/Randomized participants.

VI.4 Data Analysis

VI.4.1 Overview

Data analysis at all study stages was carried out using student's t-tests with SPSS. The means, standard deviations, mean differences and 95% confidence intervals were reported for each variable evaluated. At baseline, the data reveal the participants' widely differing perceptions about their complete dentures prior to trying out the attachment. However, the 3-month follow-up analysis provides results of data collected after each participant group used their attachments for three consecutive months.

VI.4.2 Baseline Data

The analysis values from the baseline data can be seen in Table 2;

- ***OHIP-20 Questionnaire****:*

The OHIP-20 questionnaire is measured on a scale from 20 to 120. We found that the mean for the participants group who wore the Novaloc was 77 (SD=24), while the mean rating of those who wore the Locator was 95 (SD=21). A mean difference of -18 between the two groups was detected, along with the 95 % CI measuring -51 to 15, which provides no evidence of between-group difference.

- ***Satisfaction Questionnaire:***

For the nine variables assessed in this VAS questionnaire, the differences were not significant except in two of the aspects measured as shown in Table 2; (1) "*Ease of cleaning*" and, (2) "*Ability to chew-hard cheese*". Regarding *"General satisfaction*", the group wearing the Novaloc rated it at a mean of 6.5 with a SD of 3.9, while the group wearing the Locator rated it at a mean of 9.1 and an SD of 0.50. The high SD and wide 95% CI for the Novaloc (NL) group reflects the high variation in the within the NL group.

- ***The effect of oral condition on the general health:***

From all ten patients included at baseline; four answered with a "Yes" and the remaining six answered "No". Three out of the four who replied with a "Yes" were in the group receiving the Novaloc attachment. Those who responded with "Yes" provided reasons, such as; (1) limitations in food choices (i.e. less fresh vegetables and fruits) and (2) difficulty digesting due to improper chewing.

Table 2. Baseline Data. *: Significant values

Variable	Attachment	Mean (SD)	Mean Difference	95% CI of the difference
OHIP-20 SUMMARY:				
	NL (Novaloc)	77 (24)	-18	-51 to 15
	LO (Locator)	95 (21)		
SATISFACTION QUESTIONAIRE:				
1. Ease of cleaning	NL (Novaloc)	8.9 (0.5)	**-0.8***	**-1.4 to -0.2***
	LO (Locator)	9.8 (0.3)		
2. General Satisfaction	NL (Novaloc)	6.5 (3.9)	-2.7	-7.5 to 2.2
	LO (Locator)	9.1 (0.5)		
3. Ability to speak	NL (Novaloc)	7.0 (3.4)	-3.0	-7.2 to 1.2
	LO (Locator)	10.0 (0.0)		
4. Comfort	NL (Novaloc)	5.8 (3.6)	-3.2	-7.6 to 1.1
	LO (Locator)	9.1 (0.8)		
5. Aesthetics	NL (Novaloc)	7.6 (2.6)	-2.4	-5.6 to 0.8
	LO (Locator)	9.9 (0.1)		
6. Stability	NL (Novaloc)	3.9 (3.8)	-4.6	-9.3 to 0.1
	LO (Locator)	8.5 (1.3)		
7. Ability to chew:				
7.1. Difficult to chew food in general?	NL (Novaloc)	5.1 (3.3)	-3.8	-7.9 to 0.2
	LO (Locator)	8.9 (0.5)		
7.2. Fresh white bread	NL (Novaloc)	6.2 (3.6)	-3.4	-7.9 to 1.0
	LO (Locator)	9.6 (0.4)		
7.3. Hard cheese	NL (Novaloc)	5.2 (3.2)	**-4.1***	**-8.0 to -0.1***
	LO (Locator)	9.3 (0.9)		
7.4. Raw Carrots	NL (Novaloc)	3.1 (3.6)	-2.4	-9.6 to 4.9
	LO (Locator)	5.5 (4.8)		
7.5. Dry salami	NL (Novaloc)	4.3 (3.5)	-0.3	-6.3 to 5.7
	LO (Locator)	4.6 (3.0)		
7.6. Sliced steak	NL (Novaloc)	3.2 (3.6)	1.1	-6.4 to 8.5
	LO (Locator)	2.1 (2.7)		

7.7. Raw Apples	NL (Novaloc)	2.9 (2.5)	-3.5	-8.5 to 1.5
	LO (Locator)	6.4 (3.3)		
7.8. Lettuce	NL (Novaloc)	4.1 (3.1)	-2.3	-6.7 to 2.1
	LO (Locator)	6.4 (2.2)		
8. Function:				
8.1. Is your food well chewed before swallowing in general?	NL (Novaloc)	4.6 (3.7)	-2.9	-8.0 to 2.3
	LO (Locator)	7.5 (3.4)		
8.2. Fresh white bread	NL (Novaloc)	6.4 (3.7)	-1.5	-5.8 to 2.8
	LO (Locator)	7.9 (1.6)		
8.3. Hard cheese	NL (Novaloc)	5.7 (3.4)	-1.3	-6.0 to 3.4
	LO (Locator)	7.0 (2.3)		
8.4. Raw Carrots	NL (Novaloc)	5.7 (3.4)	-2.0	-9.1 to 5.2
	LO (Locator)	7.0 (2.3)		
8.5. Dry salami	NL (Novaloc)	3.0 (3.7)	-1.7	-8.4 to 5.1
	LO (Locator)	4.9 (4.5)		
8.6. Sliced steak	NL (Novaloc)	3.3 (3.5)	-2.0	-8.6 to 4.7
	LO (Locator)	5.0 (0.7)		
8.7. Raw Apples	NL (Novaloc)	3.3 (3.5)	-0.7	-7.8 to 6.4
	LO (Locator)	5.2 (4.1)		
8.8. Lettuce	NL (Novaloc)	3.7 (3.3)	-2.6	-8.0 to 2.7
	LO (Locator)	6.3 (3.5)		
9. Oral condition	NL (Novaloc)	5.3 (3.7)	-3.9	-8.0 to 0.2
	LO (Locator)	9.2 (1.4)		

VI.4.3 Three-Month Follow-up

The results of the analysis for the Novaloc and the Locator group after three months are shown in Table 3.

- ***OHIP-20 Questionnaire:***

The mean values for both the Novaloc (109) and Locator group (107) are somewhat similar, and the standard deviation (SD= 7 for the Novaloc, SD= 5 for the Locator) is seen to be smaller. The difference in means between the two groups (5.0) with the corresponding 95% CIs (-4 to 15) is not significant.

- ***Satisfaction Questionnaire:***

At the three months follow up, 10 variables were assessed, instead of 9 because the 10th included items regarding the denture's rotation. None of the factors examined showed a significant difference in performance between the Novaloc and the Locator groups. After 3 months of wearing the SIMOs, results show signs of outlier values for one participant. This resulted in a higher standard deviation, which subsequently affected the variable outcomes. The mean "*general satisfaction*" of the NL group was 9.2 with a SD of 1, while for the LO group the mean was 8.6 with a 1.9 standard deviation. Regarding the *ability to chew* "raw carrots, sliced steak, dry salami and raw apples", both groups had lower mean ratings with a higher standard deviation Concerning *rotation of the denture*, 4 of the 9 patients examined at the 3-month follow-up answered with a "Yes" and the remaining five with a "NO". Three out of the four who answered yes were in the NL group. Regarding the five patients who answered "No"; three wore the LO and the other 2 wore the NL attachment.

- ***The effect of the oral condition on general health:***

At the 3-month follow-up, only one participant from the LO group answered "Yes". However, this patient reported a positive effect of his oral health on the general health, explaining that he was able to chew better and therefore, digest food easier.

Table 3. 3-Month Follow-up Data

Variable	Attachment	Mean (SD)	Mean Difference	95% CI of the difference
OHIP-20 SUMMARY:				
	NL (Novaloc)	109 (7.0)	5.0	-4 to 15
	LO (Locator)	104 (5.0)		
SATISFACTION QUESTIONAIRE:				
1. Ease of cleaning	NL (Novaloc)	8.4 (2.3)	-0.9	-3.8 to 2.0
	LO (Locator)	9.3 (1.0)		
2. General Satisfaction	NL (Novaloc)	9.2 (1.0)	0.7	-1.6 to 2.9
	LO (Locator)	8.6 (1.9)		
3. Ability to speak	NL (Novaloc)	9.1 (0.9)	-0.3	-1.5 to 0.9
	LO (Locator)	9.4 (0.5)		
4. Comfort	NL (Novaloc)	9.1 (0.9)	0.4	-1.5 to 2.3
	LO (Locator)	8.7 (1.5)		
5. Aesthetics	NL (Novaloc)	9.0 (0.9)	0.3	-1.3 to 1.9
	LO (Locator)	8.8 (1.2)		
6. Stability	NL (Novaloc)	8.3 (0.8)	1.4	-0.4 to 3.2
	LO (Locator)	6.9 (1.5)		

7. Ability to chew:				
7.1. Difficult to chew food in general?	NL (Novaloc)	8.8 (0.7)	0.7	-1.6 to 3.0
	LO (Locator)	8.1 (2.1)		
7.2. Fresh white bread	NL (Novaloc)	9.1 (0.7)	-0.3	-1.4 to 0.8
	LO (Locator)	9.4 (0.7)		
7.3. Hard cheese	NL (Novaloc)	8.9 (1.0)	0.9	-1.6 to 3.5
	LO (Locator)	7.9 (2.2)		
7.4. Raw Carrots	NL (Novaloc)	6.8 (3.3)	2.0	-2.9 to 6.9
	LO (Locator)	4.8 (2.9)		
7.5. Dry salami	NL (Novaloc)	7.3 (3.9)	3.3	-2.8 to 9.3
	LO (Locator)	4.1 (3.1)		
7.6. Sliced steak	NL (Novaloc)	7.3 (3.9)	-0.7	-5.8 to 4.4
	LO (Locator)	8.0 (2.0)		
7.7. Raw Apples	NL (Novaloc)	7.1 (2.0)	0.0	-3.7 to 3.6
	LO (Locator)	7.1 (2.6)		
7.8. Lettuce	NL (Novaloc)	8.6 (2.2)	0.2	-2.9 to 3.2
	LO (Locator)	8.4 (1.5)		
8. Function:				
8.1. Is your food well chewed before swallowing in general?	NL (Novaloc)	7.7 (2.9)	-0.7	-4.4 to 3.1
	LO (Locator)	8.4 (1.2)		
8.2. Fresh white bread	NL (Novaloc)	8.8 (0.8)	0.6	-1.1 to 2.3
	LO (Locator)	8.2 (1.3)		
8.3. Hard cheese	NL (Novaloc)	9.0 (0.5)	1.2	-3.4 to 5.9
	LO (Locator)	7.8 (3.0)		
8.4. Raw Carrots	NL (Novaloc)	6.4 (4.0)	0.1	-5.0 to 5.2
	LO (Locator)	6.4 (2.2)		

8.5. Dry salami	NL (Novaloc)	6.6 (4.1)	1.2	-4.3 to 6.6
	LO (Locator)	5.5 (2.1)		
8.6. Sliced steak	NL (Novaloc)	7.1 (3.2)	0.4	-4.4 to 5.3
	LO (Locator)	6.7 (2.8)		
8.7. Raw Apples	NL (Novaloc)	7.6 (3.4)	-0.8	-5.1 to 3.6
	LO (Locator)	8.4 (1.6)		
8.8. Lettuce	NL (Novaloc)	7.8 (3.5)	-0.4	-4.9 to 4.1
	LO (Locator)	8.3 (1.3)		
9. Oral condition	NL (Novaloc)	8.4 (1.8)	0.1	-2.3 to 2.5
	LO (Locator)	8.3 (1.0)		
10. How much does the lifting of the denture bother you? 0 (Not bothered)-10 cm (extremely bothered)	NL (Novaloc)	4.7 (4.4)	3.2	-2.7 to 9.2
	LO (Locator)	1.5 (2.0)		

VI.5 Partial outcomes – patient preferences

Although only 5 participants completed the cross-over stage, most of them (4, or 80%) preferred the Novaloc attachment. Novaloc was the second attachment used for 2 of them, whereas the other 2 participants requested to have their Locators replaced by Novaloc. Just one participant preferred the Locator, which was the second attachment used (no change was made).

This partial sample yields 95% confidence intervals (95% CI) ranging from 38% to 96%.If the same proportion of participants choose to keep the Novaloc attachment at the end of the trial (n=15), this would indicate that preferences are not random (i.e. >50%). Such an updated sample size would result in a 95% CI from 55% to 93%.

VI.6 Withdrawals and Losses

At present, no participant has withdrawn from the trial or requested any modification in the interventions. One participant was lost to follow-up. However, the reason for this is completely unrelated to the study, i.e., a glioblastoma that evolved to death, following implant placement and before attachment insertion/allocation.

One participant had a failed implant. This participant is currently waiting for 3 months before placement of new implant in her/his healed ridge.

VII. DISCUSSION

VII.1. Overview

This randomized clinical trial was conducted to provide clinical evidence regarding the performance of the newly developed Novaloc attachment. The characteristics of that new attachment can potentially improve the outcomes of single implant retained overdentures for the edentate elderly patient. The trial compares Novaloc (the intervention of interest) to the Locator system as an active comparator. Resulting evidence will help guide clinicians and patients through treatment planning when considering a lower SIMO.

This thesis has described the primary part of this study by showing the generalizability and viability of the study sample. It also provides preliminary evidence during the first 3-months with each attachment, in the assessment of the Novaloc vs. Locator attachment systems. This assessment was carried out through evaluating patient-reported outcomes, including satisfaction with a SIMO (as a primary outcome) and other secondary aspects such as the oral health-related quality of life. The need for this study is reinforced by its uniqueness – our literature review has shown no previous or ongoing RCTs that assessed the Novaloc on a lower SIMO or other treatment approaches.

VII.2. Summary of Findings & Evidence

Screening has followed a steady pace, with a favourable percentage of recruited individuals. Out of the total 38 individuals initially screened, 11 (30%) were included. However, one patient lost his implant and is rescheduled to have it replaced. Thus, 10 participants were included for baseline analysis and 9 patients for the 3-month follow up. The excluded individuals were eliminated from the study, mostly due to systemic conditions that contraindicate minor oral surgery. The majority of participants were recruited by contacting former denture patients from the student dental clinic at McGill University. The proportions of females to males recruited, screened and analyzed throughout the study remained somewhat equivalent. In general, our participant profile is close to that expected for mandibular two-implant overdenture patients [42]. This includes sociodemographic factors, systemic health status, radiographic appearance and the need for adequate complete dentures.

Despite the partial results at this time, current outcome data deserve comment because they suggest a coherent set of responses by participants, with equilibrium between treatment arms from baseline to the 3-mo (i.e., first) follow-up.

Primary Outcome Data encompass *general patient satisfaction with the mandibular complete denture*, as measured through a VAS questionnaire. At baseline, participants who received Novaloc rated their satisfaction with a mean of 6.5 and a 3.9 SD; those to receive Locator was rated with a mean of 9.1 and a 0.5 SD. These values suggest a difference, but the wide variation, as well as the reduced sample size do not allow for significance. Some factors are thought to be related to such data variations, including the existence of an outlier – one participant in the group

receiving the Novaloc attachment gave atypically low ratings. Moreover, the heterogeneous, relatively small sample considered in this thesis leads to broad confidence interval ranges, thus demonstrating a wide variation of assumptions and conclusions.

It should be taken into consideration that, depending on need, participants had their dentures either repaired or fully replaced prior to proceeding in the study. In addition to the factors mentioned earlier, previous prosthetic treatment justifies the varying discrepancy in the ratings for general satisfaction in this study. Other studies evaluated patient's satisfaction with conventional CDs [43-46]; one [43] revealed low mean scores for general satisfaction with high SDs. Such results were likely related to involving a larger, more inclusive sample of 120 patients that specifically complained about their current CDs and requested replacements [43]. Another longitudinal study examined the general satisfaction of 22 patients with their newly fabricated complete dentures, and its association to OHRQoL; it showed a mean satisfaction of 7.7 (SD=2.5) at baseline and 8.2 (SD= 2.2) at the 6-month follow-up. These results are closer to the values in our study due to certain similarities, including a small sample size, patients with new complete dentures and in the same age range [44]. In a Turkish study, 342 participants (age range: 39 to 89 years) received new complete dentures and provided data about their general satisfaction and the factors related to it (e.g., years of denture wearing and patient ages). Again, general satisfaction was measured on a 10-cm VAS, with a mean of 6.9 and a 2.0 SD in the first three years of denture wearing, and a significantly higher satisfaction in the period that exceeds 3 years [45]. The results of this study suggest the following assumption relating to our thesis: when new complete dentures are inserted, a large group of patients tend to report similar satisfaction, with probable outliers with low satisfaction values. The occurrence of those outliers in a small sample will appear more

prominently, as observed in this study. This aspect must be considered for descriptive statistics and data analysis by contraindicating traditional parametric approaches.

At the *3-month follow-up*, general patient satisfaction with SIMOs reached a mean of 9.2 (SD: 2.0) for the group of patients with the Novaloc attachment, and 8.6 (1.9) for those with the Locator. Those results were close (no significant difference), with improvement from baseline for the outlier and, thus, almost similar mean values and SDs. Furthermore, looking at the results for the overall VAS questionnaire for 3-month satisfaction, we see that the sample has maintained its heterogenicity detected at baseline. A randomized cross over trial performed in China that closely resembles the present study's design and outcomes examined two attachments (Locator vs. Magfit) on a SIMO [47]. It analysed 12 patients for overall satisfaction and masticatory ability, with results comparable to ours. Overall satisfaction for the Locator and Magfit attachments were close (non-significant differences). However, the sample size of the Chinese study is likely to have been underpowered to detect clinically relevant differences [47]. Our study estimates a sample size twice as larger for sufficient power, with a similar outcome variable.

A larger sample and different design may increase the likelihood of non-rejection of our null hypothesis, in case of similar outcome variables. A retrospective study [48] evaluated the satisfaction and quality of life of 62 edentulous participants that previously received implant overdentures (different numbers) with several types of attachments. It was concluded that there was no significant difference in patient satisfaction regarding the attachment (Locator or Ball) used, regardless of the number of implants placed [48].

Secondary outcomes included a series of patient-reported outcome sets, including OHRQoL evaluated through the OHIP-20E questionnaire, additional satisfaction parameters (e.g., denture

stability, retention, comfort, functionality and ease of cleaning) and denture rotation (only at the 3-month follow up).

At *baseline*, mean OHIP-20E questionnaire scores were 77 (SD 24) for participants receiving the NL and 95 (SD 21) with LO, with no significant differences. Those values reflect a wide variability in OHRQoL before the SIMO is provided. Outliers were common, creating a potential impact on the sample size needed to detect relevant differences. In other words, a limited number of participants may produce imprecise between-treatment comparisons.

In most cases, the other items in the denture satisfaction questionnaire resulted in similar between-group results. The only two items that showed a significant difference between the two groups receiving the NL and LO were "ease of cleaning" and the "ability to chew hard cheese". However, as stated earlier, this significance may have been a result of the sample heterogeneity and presence of atypical responses from at least one participant. The likelihood of a type I statistical error should also be considered, given the large number of simultaneous comparisons.

At the *3-month follow-up*, results for OHRQoL seem to have changed more considerably than patient satisfaction, with more favourable OHRQoL scores. Mean scores (+SD) after attachment insertion were: NL: 109 (7) and LO: 104 (5), with no significant difference. The post-treatment findings are more consistent, with low data variance. These OHIP scores demonstrate that both groups reached a certain homogeneity, especially when compared to baseline results. Another previously-mentioned study examined the OHRQoL of 62 edentulous participants; this report showed that OHIP scores are sensitive to changes in implant attachment types and number [48]. However, authors of a study, in which the OHRQoL for 58 patients were evaluated, reported that attachment type has no significant effect on the OHRQoL of patients with implant dentures [49]. In any case, our findings suggest that the post-study between-treatment comparisons at the end of

the study may be much more precise . A potential benefit will be the possible detection of relatively smaller differences, if they exist.

Other parameters for satisfaction: From the ten variables assessed, there were no significant difference between patients wearing the NL and LO attachments. As opposed to the results of the OHRQoL, the satisfaction questions showed consistent variation patterns in both groups of participants after 3 months of wearing their SIMOs. Concerning perceived rotation, the mean and the standard deviation for participants with the NL attachment who complained about denture lifting is 4.7 (SD 4.4). For LO group participants rated their perceived rotation at 1.5 (2.0 SD). Although the NL scored higher in this category, the distinctly high standard deviation seen in both groups limits our ability to reach an exact conclusion.

Further outcomes:

As mentioned earlier in the results section, at this point in the study, only five of 9 participants assessed have been evaluated at the cross-over stage. Four of the five participants chose the Novaloc attachment after trying both attachments, each for 3 months. This is promising positive feedback for the NL. Participants seem to prefer NL for more long-lasting retention; even if initial values are more modest compared to the LO, both the absolute and the % of loss in retention forces are much lower with the NL [50, 51]. That likely had an effect on patient preferences over.

VII.3. Limitations

Several factors could weaken the integrity or reliability of the results:

1- The sample size used for the analysis undertaken in this thesis is smaller than what is aimed for. Therefore, any assumption regarding the performance of each attachment should be made carefully. However, it serves as an internal pilot to support the viability of the RCT.

2- Outlier values for specific patients might have produced inaccurate outcomes. This issue will be handled in the future by increasing the sample size and, thus, have a more even distribution of atypical results when both attachments are used. The cross-over design may provide data for both attachments coming from each participant, including those with non-standard responses. Finally, the qualitative approach and subsequent mixed methods analysis may unveil differences between the two attachments with a relatively small sample. Patient preferences show a trend towards the NL attachment, and we do not expect many new topics to emerge from future qualitative assessments at the 6-mo follow-up.

3- One participant was lost due to a rapid progressing cancer in the brain (glioblastoma) before he completed the first follow-up and having his attachment placed. That is a risk for virtually any clinical trial. Thus far, we have had few issues with that loss, and compliance by the remaining participants has been relatively high with study appointments and treatment maintenance. Demise in such conditions leads to a “missing completely at random” situation. Situations like unhappy participants leaving the study due to dissatisfaction with received attachments would be much more problematic in terms of data management and analyses.

4- One participant's implant required replacement. Although we followed all the manufacturer recommendations, including a period of at least 28 days for non-immediate loading, this study uses a narrower than normal implant, and just one. Those situations may lead to slightly higher risk of implant failure over time, lacking primary and secondary stability within the first few weeks. One participant's implant was gently rotated during the insertion of his first attachment (maximum torque: 35 N.cm); insertion and loading were aborted, and we made sure that any new torqueing on that implant would happen after three months, as long as the biological environment has not significantly changed. Since then, this implant has been evaluated with PA radiographs each 3 months; the images suggest that the bone healing is favourable; abutments have been attached and torqued to 35 N.cm with no additional events.

VIII. CONCLUSION

This thesis describes the preliminary data of an RCT in which the Novaloc and Locator attachment on a SIMO are compared by edentulous elderly patients. This pilot study provides sound evidence regarding the study feasibility and recruitment.

Our participant exclusion criteria are the same as those used in clinical practice. Our experience in recruiting participants for this study demonstrates that a large number of systemically ill patients may not receive even a SIMO, no less a prosthesis retained by two or more implants. Initially, 38 people were examined; 17 were included, and the remaining were mainly excluded for multiple systemic conditions contraindicating a minor oral surgery.

Although not many conclusions can be drawn from follow-up data at this time, general findings suggest, that there is no difference between participants assigned to the NL and LO group at baseline and at 3 months follow up for general satisfaction and OHRQoL scores. At first glance, these findings suggest a balanced allocation at baseline, followed by modest differences after the cross-over is concluded. However, the tendency for participants to prefer Novaloc and who choose to use it on the long-term suggests that the NL may be the preferred attachment. However, at this stage of the study, we are not able to reach a conclusive result on which attachment is superior to the other. Qualitative assessment will shed light on such possible preferences and their reasons for them.

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Appendices

Appendix A

Appendix A.1: Magazine advertisement (English)

McGill

Clinical Trial

DO YOU WANT MORE STABLE DENTURES??

Our research group at McGill University is looking for participants to **study the tightness of lower dentures retained by a single dental implant.**

You can submit your name and receive a **free** single implant if you fit the following criteria:

- **Are aged 65 years or over;**
- **Have no natural teeth for at least 6 months;**
- **Have a complete set of dentures in good condition;**
- **Are in relatively good health and able to clean your dentures.**

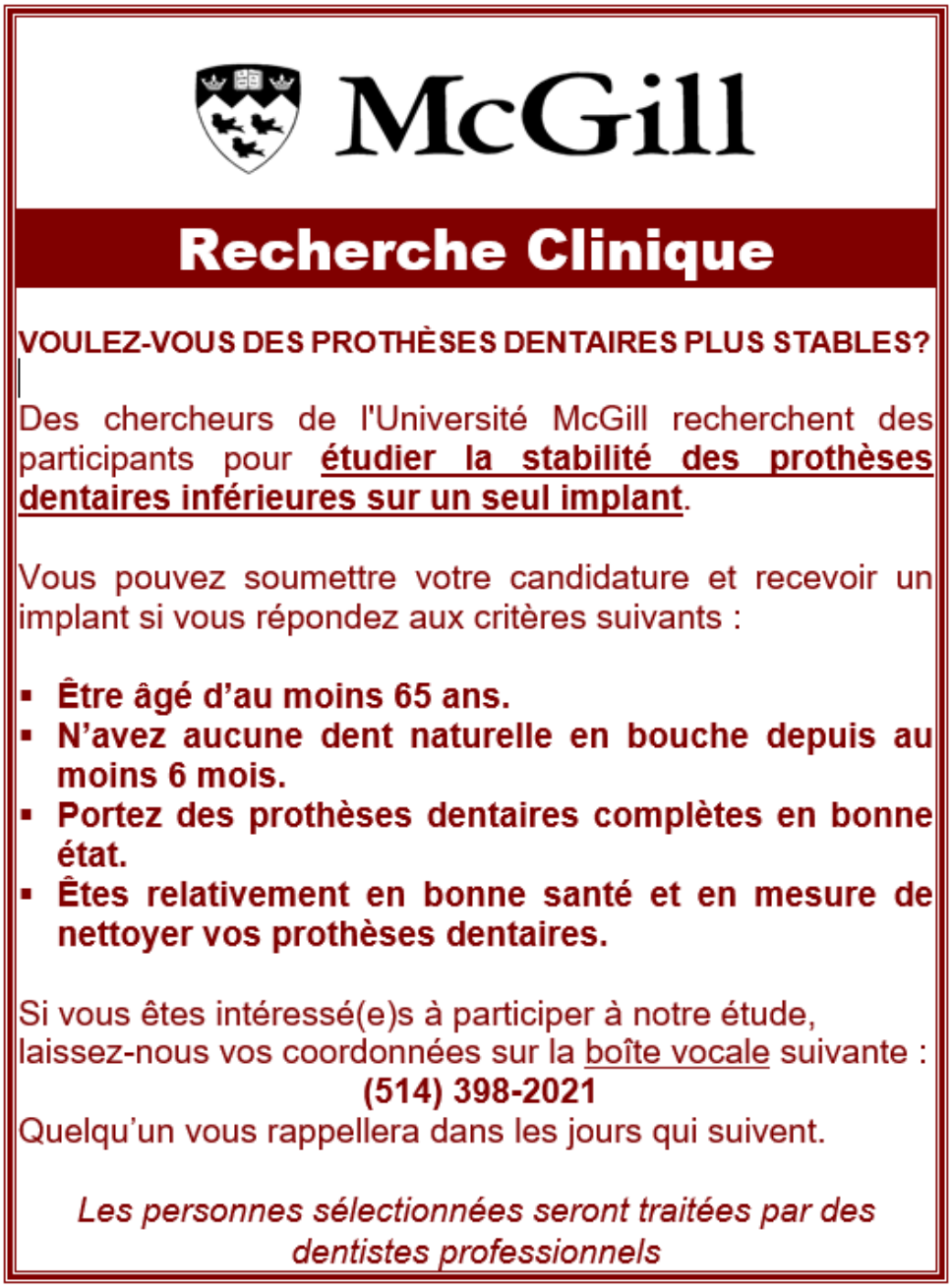
If you are interested in hearing more about our study, please leave your name and telephone number on the following voice mail:

(514) 398-2021

Your call will be returned in the following days.

Selected participants will be treated by trained and qualified dentists.

Appendix A.2: Magazine advertisement (French)



McGill

Recherche Clinique

VOULEZ-VOUS DES PROTHÈSES DENTAIRES PLUS STABLES?

Des chercheurs de l'Université McGill recherchent des participants pour **étudier la stabilité des prothèses dentaires inférieures sur un seul implant**.

Vous pouvez soumettre votre candidature et recevoir un implant si vous répondez aux critères suivants :

- **Être âgé d'au moins 65 ans.**
- **N'avez aucune dent naturelle en bouche depuis au moins 6 mois.**
- **Portez des prothèses dentaires complètes en bonne état.**
- **Êtes relativement en bonne santé et en mesure de nettoyer vos prothèses dentaires.**

Si vous êtes intéressé(e)s à participer à notre étude, laissez-nous vos coordonnées sur la boîte vocale suivante :

(514) 398-2021

Quelqu'un vous rappellera dans les jours qui suivent.

Les personnes sélectionnées seront traitées par des dentistes professionnels

Appendix A.3: McGill undergrad clinic announcments (English & French)

McGill
Faculty of Dentistry

(La version française suit)

Montréal, 11-02-2019

Dear Sir/Madam,

The Faculty of Dentistry of McGill University is participating in a research project, which goal is to study if dental implants could improve the satisfaction of patients who are wearing a complete lower denture. Many patients using a complete lower denture have difficulties wearing it because of looseness and discomfort. This study may help patients, and provided them with a more stable lower denture.

If you received a complete lower denture in our clinic during the last few years, you may be eligible to participate. You do not need to make an application for this right now. The coordinator of this study (Miss Gabrielle Mariano) may contact you by phone or letter during the next six months. She will explain the criteria for participation and the steps of this study (minimum of 7 visits).

Participation is voluntary. You may refuse to participate or withdraw from the study at any time, and this would not affect your dental care in any way.

If you prefer, you may leave a voice message with your coordinates to Miss Mariano at (514) 398-7203, ext. 0199, or send an e-mail (gabrielle.mariano@mail.mcgill.ca).

Thank you,

Nathalie Morin, Clinic Director

Madame/Monsieur,

La Faculté de Médecine Dentaire de l'Université McGill participe à un projet de recherche qui a pour but d'étudier si des implants dentaires peuvent augmenter la satisfaction des patients portant une prothèse complète inférieure. Plusieurs personnes utilisant une prothèse complète inférieure, éprouvent des difficultés à la porter puisqu'elle bouge et est inconfortable. Cette étude pourrait aider les patients, en leur procurant une prothèse complète inférieure plus stable.

Si vous avez reçu une prothèse complète inférieure à notre clinique au cours des dernières années, vous êtes possiblement admissible à participer. Vous n'avez pas besoin de nous contacter pour faire une demande de participation. La coordonnatrice de cette étude (Mme Gabrielle Mariano) pourrait vous contacter par téléphone ou par lettre d'ici six mois. Elle va vous expliquer les critères de l'étude et les étapes requises pour une éventuelle participation (minimum de 7 visites).

Votre participation est volontaire. Vous pourrez refuser de participer ou abandonner le projet à tout moment, et cela n'affectera en rien vos soins dentaires.

Si vous préférez, vous pouvez laisser un message vocal avec vos coordonnées pour Mme Mariano au (514) 398-7203, ext. 0199, ou bien lui envoyer un courriel (gabrielle.mariano@mail.mcgill.ca).

Merci,

Nathalie Morin, Directrice des Cliniques

Appendix B

Appendix B.1: Screening Form

McGill University - Faculty of Dentistry
Research Protocol: Single-implant overdentures retained by the Novaloc attachment system: a mixed methods randomized cross-over trial

Patient Name

Screening Criteria Checklist Form

☐☐☐☐ / ☐☐ / ☐☐
y y / m m / d d

Is the patient eligible? YES ○ NO ○

Identification							
Name:	1.						
Address: (street, number, apt.)	2.			**City**	3.		
				Postal Code:	4.		
Phone numbers:	5. Home:		6. Work:		7. Cell:	8. Other (specify):	
Date of birth:	_____/_____/_____ (dd) (mm) (yyyy)	**Age:**	_____years	**Participant code (if eligible):**			

Inclusion Criteria **(Checked during initial contact and brief clinical exam) – One 'no' precludes inclusion and will be used as the reason.**

9. Completely edentulous for six months or more (ask the patient and then check with clinical exam)? ☐ Yes ☐ No

10. Accepts implant Tx (after explanation)? ☐ Yes ☐ No

11. Space in the mandible (clinical exam, confirm with CBCT)?
→3.3 mm wide implant in the midline ☐ Yes ☐ No

12. Able to maintain adequate oral/denture hygiene (mark 'no' if there is any important neurological disease or abundant denture plaque. In doubt, 50% or more of plaque after the use of a disclosing solution precludes inclusion, as well as spread stains and calculus)?
☐ Yes ☐ No

13. Adequate general health (check if systemic health permits minor oral surgery)?
☐ Yes ☐ No

If no, why:_____

14. Understands written and spoken English or French?
☐ Yes ☐ No

15. Accepts/is able to give written informed consent?
☐ Yes ☐ No

16. Acceptable dentures? ☐ Yes ☐ No (according to the criteria below):

17. Fractured bases or teeth? ○ Yes ○ No

18. Vertical dimension (esthetics and interocclusal distance- FS<7mm)? ○ Adequate ○ Inadequate

19. Tooth wear: ○ None ○ Flat wear facets ○ 1/3 worn ○ >1/3 worn

20. Border extension/fit? ○ Adequate ○ Inadequate

Exclusion Criteria **(To be filled after brief clinical exam and radiographic assessment) – Any 'yes' indicates exclusion and will be cited as the reason in the flowchart .**

CLINICAL CRITERIA

21. Any serious or severe illness that require frequent hospitalization?

☐ Yes ☐ No

22. Impaired cognitive function? ☐ Yes ☐
No

23. Unable to return for study recalls? ☐ Yes ☐
No

24. Radiation therapy to the orofacial region? ☐ Yes ☐
No
(past or present)

25. Specific conditions or habit that may jeopardize treatment (alcoholism, smoking > 10 cigarettes/day, others…)? ☐ Yes ☐
No

If yes, what:_____

26. Evidence of chronic or acute parafunctional disorders or TMD?

☐ Yes ☐ No

27. Previous implant treatment? ☐ Yes ☐
No

RADIOGRAPHIC CRITERIA - CBCT

28. Bony pathologic lesions? ☐ Yes ☐
No

29. Vertical bone height < 11mm or insufficient width? ☐ Yes ☐
No
→ Symphyseal region

30. Evident endosseous vascular structures? ☐ Yes ☐
No
→ Refer to Kalpidis & Setayesh. J Periodontol. 2004;75:631-45.

31. Cawood and Howell class I or II? ☐ Yes ☐
No
→ Int J Oral Maxillofac Surg. 1988 Aug;17(4):232-6.

Comments:

Appendix B.2. Cost Analysis Form- prosthetic/Surgical procedures

McGill University - Faculty of Dentistry
Research Protocol: Single-implant overdentures retained by the Novaloc attachment system: a mixed methods randomized cross-over trial

(5.A) Cost analysis – sugical/prosthetic procedures

Attachment Type: ○ NL ○ LA

☐☐☐☐ / ☐☐ / ☐☐
year mm dd

Stage: Pre-load ○ 3 mo ○ 6 mo ○ 18 mo ○ Other (specify): _____

Performed procedures:	

CLINICAL TIME:

	Start	**End**
Application of consent form:		
Operator:		
Assistant*:		
Laboratory*:		
Others (specify:_____)†:		

*If n/a, mark "0"(zero) or cross-out; †Count any outcome data assessment done on baseline here.

MATERIAL*:

Equipment:	○ Clinical exam instruments ○ Attachment kit ○ Surgical Handpiece ○ Standard handpiece and burs ○ Surgical instruments ○ Surgical kit - implants ○ Prosthetic kit – implants ○ Digital radiograph (n, 'PA':___ or 'Pan':___)	○ Laboratory bench lathe ○ Scaling instruments ○ Others:_____ _____ _____

	Type	Brand name/Specific type	Quantity
Consumables:	○ Cotton		
	○ Gauze		
	○ Suturing		
	○ Scalpel blade		
	○ Osteotomy drills, implant		
	○ Relining resin		
	○ Attachment components		
	○ Other (specify):		
Medication (pills or mouthwash):			

*If none, mark "0"(zero) or cross-out.

INDIRECT COSTS - PATIENT:

		Start		End	
Time (since waiting in the waiting room):					
	Method	**Transport Expenses** ***Time (arrival / departure)***		**Cost of tickets or trip (if applicable)**	**Lenght (km, towns, what patient remembers)**
	○ Walking	/			
	○ City bus, van or metro	/			
	○ Intercity bus or van	/			
	○ Car (self-owned or lift)	/			
	○ Taxi or Uber	/			
	○ Train				
	○ Others: _____	/			

Appendix B.3. Cost Analysis Form-Follow-up

McGill University - Faculty of Dentistry
Research Protocol: Single-implant overdentures retained by the Novaloc attachment system: a mixed methods randomized cross-over trial

(5.B) Cost analysis – follow-up

Attachment Type: ○ NL ○LA

☐☐☐☐ / ☐☐ / ☐☐
year mm dd

Stage: Pre-load ○ 3 mo ○ 6 mo ○ 18 mo ○ Other (specify): _____

Is this a scheduled visit? ○ Yes ○No

Reason of the visit:	
Procedures:	

CLINICAL TIME:

	Start	End
Operator:		
Assistant*:		
Laboratory*:		
Others (specify:_____)†:		

*If n/a, mark "0"(zero) or cross-out; †Count any outcome data assessment here.

MATERIAL*:

Equipment:	○ Clinical exam instruments ○ Attachment kit ○ Standard handpiece and burs ○ Surgical instruments ○ Prosthetic kit – implants ○ Digital radiograph (n, 'PA':___ or 'Pan':___)	○ Laboratory bench lathe ○ Scaling instruments ○ Others:_____ _____ _____

	Type	Brand name/Specific type	Quantity
Consumables:	○ Cotton		
	○ Gauze		
	○ Relining resin		
	○ Attachment components		
	○ Other (specify):		

Medication (pills or mouthwash):	

*If none, mark "0"(zero) or cross-out.

INDIRECT COSTS - PATIENT:

	Start	End
Time (since waiting in the waiting room):		

	Method	**Transport Expenses** ***Time (arrival / departure)***		**Cost of tickets or trip (if applicable)**	**Lenght (km, towns, what patient remembers)**
	○ Walking	/			
	○ City bus, van or metro	/			
	○ Intercity bus or van	/			
	○ Car (self-owned or lift)	/			
	○ Taxi or Uber	/			
	○ Train				
	○ Others: _____	/			

Appendix C

Appendix C.1. VAS Questionnaire (English)

VAS PRACTICE QUESTIONNAIRE

Date : ☐☐☐☐ / ☐☐ / ☐☐
y y m m d d

Identification Code: ☐☐☐☐☐☐

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

Example :
50% 0 _____|_____ 100

25%	0 _____ 100	☐☐☐
80%	0 _____ 100	☐☐☐
10%	0 _____ 100	☐☐☐
45%	0 _____ 100	☐☐☐
75%	0 _____ 100	☐☐☐

ASSESSMENT OF PROSTHESIS

Date: ☐☐☐☐ / ☐☐ / ☐☐
y y m m d d

Identification Code: ☐☐☐☐☐☐☐☐

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

1. Ease of cleaning

Please indicate how difficult it is to clean your **lower** prosthesis and mouth?

Extremely difficult _____ Not at all difficult

2. General satisfaction

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

Not at all satisfied _____ Extremely satisfied

3. Ability to speak

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

Extremely difficult _____ Not at all difficult

4. Comfort

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

Not at all satisfied _____ Extremely satisfied

5. Aesthetics

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

Not at all satisfied _____ Extremely satisfied

6. Stability

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

Not at all satisfied _____ Extremely satisfied

7. Ability to chew

In general, do you find it difficult to chew food?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **fresh white bread**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **hard cheese**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **raw carrots**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **dry salami**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **sliced steak**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **raw apples**?

Extremely difficult _____ Not at all difficult

Please indicate how difficult it is for you to eat **lettuce**?

Extremely difficult _____ Not at all difficult

8. Function

In general, is your food well chewed before swallowing?

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

Are pieces of **dry salami** well chewed before swallowing?

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

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

Badly chewed _____ Very well chewed

9. Oral condition

In general, are you satisfied with your oral condition?

Not at all satisfied _____ Extremely satisfied

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

No ○$_0$ Yes ○$_1$

If yes, why?

_____

_____

_____

_____

_____

Rotation of the mandibular overdenture (skip this for baseline)

1. Does **your denture lift** at the back when you chew?

No ○$_0$ Yes ○$_1$

2. How much does the **lifting** of your denture bother you?

Not at all bothered _____ Extremely bothered

Appendix C.2. VAS Questionnaire (French)

ENTRAÎNEMENT AUX ÉCHELLES VAS

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

Code d'identification : ☐☐☐☐☐☐

Nous aimerions savoir si vous comprenez bien comment répondre aux questionnaires à l'aide d'échelles visuelles analogues. Placez un trait vertical sur la ligne horizontale à l'endroit qui représente le mieux le nombre à gauche comme dans l'exemple qui suit :

Exemple :

50% 0 ——————|—————— 100

25%	0	100	☐☐☐
80%	0	100	☐☐☐
10%	0	100	☐☐☐
45%	0	100	☐☐☐
75%	0	100	☐☐☐

ÉVALUATION DES PROTHÈSES ACTUELLES

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

Code d'identification: ☐☐☐☐☐☐☐☐☐

Nous aimerions connaître votre niveau de satisfaction face à vos prothèses actuelles. Lisez chacune des questions suivantes et placez un trait vertical sur la ligne horizontale, à l'endroit qui représente le mieux votre réponse. Si l'une des questions est sans objet ou si vous ne mangez pas certains types d'aliments, écrivez une brève explication sur la ligne.

1. Facilité à nettoyer

Éprouvez-vous de la difficulté à nettoyer votre prothèse **inférieure** et à assurer l'hygiène de votre bouche?

Difficulté extrême _____ Aucune difficulté

2. Satisfaction générale

Êtes-vous généralement satisfait(e) de votre prothèse **inférieure**?

Pas du tout satisfait _____ Entièrement satisfait

3. Capacité à parler

Éprouvez-vous de la difficulté à parler à cause de votre prothèse i**nférieure** ?

Difficulté extrême _____ Aucune difficulté

4. Confort

Êtes-vous satisfait(e) du confort de votre prothèse **inférieure** ?

Pas du tout satisfait _____ Entièrement satisfait

5. Esthétique

Êtes-vous satisfait(e) de l'apparence de votre prothèse **inférieure**?

Pas du tout satisfait _____ Entièrement satisfait

6. Stabilité

Êtes-vous satisfait(e) de la stabilité de votre prothèse **inférieure** ?

Pas du tout satisfait _____ Entièrement satisfait

7. Capacité à mastiquer

Éprouvez-vous généralement de la difficulté à manger?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger du **pain blanc frais** ?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger des **fromages durs** ?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger des **carottes crues** ?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger du **saucisson sec** ?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger du **steak en tranche**?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger des **pommes crues** ?

Difficulté extrême _____ Aucune difficulté

Éprouvez-vous de la difficulté à manger de la **laitue**?

Difficulté extrême _____ Aucune difficulté

8. Fonction

Les morceaux de nourriture sont-ils généralement bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **pain blanc frais** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **fromage dur** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **carottes crues** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **saucisson sec** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **steak en tranche** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **pommes crues** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

Est-ce que les morceaux de **laitue** sont bien mâchés avant d'être ingurgités ?

Très mal mâchés _____ Très bien mâchés

9. Condition buccale

En général, êtes-vous satisfait(e) de votre condition buccale ?

Pas du tout satisfait _____ Entièrement satisfait

D'une manière générale, pensez-vous que votre condition buccale a un effet négatif sur votre état de santé ? Non ○$_0$ Oui ○$_1$ Dans l'affirmative, pourquoi? _____ _____ _____ _____ _____	

Rotation de la prothèse inférieure sur implant (avant les attachements : passer sur ces questions) **1.** Est-ce que votre **prothèse inférieure s'élève** à l'arrière pendant la mastication? Non ○$_0$ Oui ○$_1$ 2. **Combien la levage** de votre prothèse vous dérange? Pas du tout dérangé _____ Entièrement dérangé	

Appendix C.3. OHIP-20E Questionnaire (English)

OHIP-20E Questionaire

Identification code : ☐☐☐☐☐☐☐☐☐☐

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

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

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

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

Appendix C.4. OHIP-20E Questionnaire (French)

QUESTIONNAIRE OHIP-20E

Code d'identification : ☐☐☐☐☐☐☐☐☐☐

Date : ☐☐☐☐ / ☐☐ / ☐☐
a a m m j j

Ce questionnaire vise à évaluer combien votre condition buccale a affecté votre vie quotidienne au cours du dernier mois. À chacune des questions suivantes, cochez la case qui correspond le mieux à votre sentiment.

	Au cours du dernier mois:	**Toujours**	**Très souvent**	**Souvent**	**Occasion-nellement**	**Rarement**	**Jamais**
1	Avez-vous éprouvé de la difficulté à mastiquer des aliments à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
2	Les aliments sont-ils restés coincés entre vos dents ou dans vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
3	Avez-vous eu l'impression que vos prothèses étaient mal ajustées ?	O 1	O 2	O 3	O 4	O 5	O 6
4	Avez-vous eu de la douleur au niveau de la bouche ?	O 1	O 2	O 3	O 4	O 5	O 6
5	Avez-vous éprouvé de la difficulté à consommer certains types d'aliments à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
6	Avez-vous remarqué des points sensibles dans votre bouche ?	O 1	O 2	O 3	O 4	O 5	O 6
7	Vos prothèses ont-elles été inconfortables ?	O 1	O 2	O 3	O 4	O 5	O 6
8	Vous êtes-vous fait du souci à cause de problèmes buccaux ?	O 1	O 2	O 3	O 4	O 5	O 6
9	Vous êtes-vous senti(e) mal à l'aise à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
10	Avez-vous évité de consommer certains types d'aliments à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
11	Votre alimentation vous a-t-elle semblé insatisfaisante à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6

	Au cours du dernier mois:	**Toujours**	**Très souvent**	**Souvent**	**Occasion-nellement**	**Rarement**	**Jamais**
12	Avez-vous été incapable de manger avec vos prothèses à cause de problèmes avec celles-ci ?	O 1	O 2	O 3	O 4	O 5	O 6
13	Avez-vous dû interrompre un repas à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
14	Avez-vous été perturbé à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
15	Avez-vous été légèrement incommodé(e) à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
16	Vous êtes vous abstenu(e) de sortir à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
17	Vous êtes-vous senti(e) plus intolérant(e) envers votre famille ou votre conjoint(e) à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
18	Avez-vous été irritable au milieu d'un groupe à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
19	Avez-vous été incapable d'apprécier la compagnie des autres à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6
20	Avez-vous pensé que la vie était généralement moins satisfaisante à cause de problèmes dus à votre dentition, à l'état de votre bouche ou à vos prothèses ?	O 1	O 2	O 3	O 4	O 5	O 6

Appendix D

Appendix D.1: Ethical approval

Click here to access – Ethical Approval Document

Appendix D.2: Consent Form

Click here to access- Consent Form

Appendix E

Appendix E.1: Published Study Protocol

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